Faculty's Biosketches

Steven A. BELINSKY, PhD

Dr. Belinsky received his undergraduate training and graduate degrees at the University of North Carolina at Chapel Hill. He then did a postdoctoral fellowship and was a Senior Staff fellow at the National Institute of Environmental Health Sciences before moving to the Lovelace Respiratory Research Institute in Albuquerque, NM in 1990. He is currently Director of the Lung Cancer Program and co-directs the Cancer Population Sciences Program for the University of New Mexico Cancer Center. He has served on numerous advisory boards for the National Institute of Environmental Health Sciences and the National Cancer Institute. Dr. Belinsky has worked in the field of tobacco carcinogenesis for >20 years and is internationally recognized for his work in lung cancer and translational studies for early detection of lung cancer. His laboratory was the first to demonstrate that the tobacco specific nitrosamine causes DNA adducts that accumulate in the lung and lead to mutation of the K-ras oncogene. His work has been extended to evaluate epigenetic mechanisms for lung cancer, specifically inactivation of genes through aberrant promoter hypermethylation. Key findings from his laboratory include, identifying the p16 tumor suppressor gene as an early event in lung, the detection of promoter methylation of specific genes up to 3 years prior to diagnosis of lung cancer, and the demonstration that inhibitors that block promoter hypermethylation can prevent lung cancer development. Currently, his research is focused on controlling lung cancer through the identification of gene targets and pathways that are disrupted during the development of this disease. These findings are translated into population-based studies for the purpose of developing intermediate biomarkers for predicting cancer risk, early detection, prognosis, and response to preventive interventions. In addition, his group is involved in conducting at both the animal and human level the evaluation of novel preventive and chemotherapy approaches to reduce the mortality from lung cancer. Dr. Belinsky has authored more than 160 publications.

Clara Derber BLOOMFIELD, MD

Dr. Bloomfield is Distinguished University Professor, William Greenville Pace III Endowed Chair in Cancer Research, and Professor of Internal Medicine in Hematology-Oncology at the Ohio State University (OSU). Prior significant academic administrative positions include Chair of the Department of Medicine at Roswell Park Cancer Institute (1989–1997) and Director of the OSU Comprehensive Cancer Center (1997–2003).

She is an internationally recognized clinical scientist whose >3 decades of research on adult leukemia & lymphoma, described in >850 publications, have changed the way we think about and treat these diseases. Her most important scientific contributions include showing (1) adult acute leukemia can be cured; (2) biomarkers, especially chromosomal abnormalities and molecular markers, can and should be used to predict outcome and select treatment in adults with acute leukemia & lymphoma; and (3) biomarkers, including gene and microRNA expression array profiles, are important to classify hematologic malignancies resulting in internationally standardized classifications for these disorders.

She has made extensive contributions to national/international professional organizations, serving on the board of directors of both the American Society of Clinical Oncology (ASCO) and the American Association of Cancer Research (AACR) and chairing the National Cancer Institute (NCI) Division of Cancer Treatment's Board of Scientific Counselors. She chaired the NCI's Progress Review Group which outlined the national agenda for research in Leukemia, Lymphoma and Myeloma. She chaired the last 2 World Health Organization Clinical Advisory Committees for Neoplastic Diseases of the Hematopoietic and Lymphoid Systems, is Past-President of the Association for Patient Oriented Research and is President of the International Association for Comparative Research in Leukemia and Related Diseases. She has received numerous prestigious honors, including election to the Institute of Medicine of the National Academy of Sciences, the 2004 AACR Joseph H. Burchenal Clinical Research Award, the 2006 ASCO Distinguished Service Award for Scientific Achievement, the 2008 Henry M. Stratton Medal of the American Society of Hematology and the 2009 ASCO David A. Karnofsky Memorial Award.

Dominique BONNET, PhD

Research Goals: Understanding the normal hematopoietic stem cell development and how this process is dysregulate in the formation of AML. Specifically try to understand the role of leukemic stem cells in the context of leukemogenesis development. Also interested in defining the role of the stem cell niche in both normal and leukemic development.

Qualifications:

PhD 1992, University Paris VII.

Postdoctoral work (1993–1996) at the Hospital for Sick Children, Toronto, Canada in Prof. John E Dick's lab.

Associate Professor (1997–2000), Coriell Institute for Medical Research, Camden, New-Jersey, USA. Joined Imperial Cancer Research Fund (now known as Cancer Research UK) in 2001. In charge of the Haematopoetic Stem Cell group as a senior Group Leader since 2006.

Marc BUYSE, ScD

Marc Buyse holds a doctorate degree in biostatistics from Harvard University and is currently Chief Executive Officer of the International Drug Development Institute (IDDI) in Louvain-la-Neuve, and Associate Professor of Biostatistics at Hasselt University in Belgium. His interests include clinical trial methodology, meta-analysis, statistical detection of fraud, validation of surrogate endpoints, and use of biomarkers in cancer drug development.

David P. CARBONE, MD, PhD

David Carbone graduated summa cum laude from Amherst College in 1977 and received an MD and a PhD in Molecular Biology and Genetics at Johns Hopkins University in 1985. He then did an Internal Medicine internship and residency at The Johns Hopkins Hospital through 1988 followed by a Medical Oncology fellowship at the National Cancer Institute in Bethesda, MD. In 1991 he was appointed Assistant Professor at the University of Texas Southwestern Medical Center and was promoted to Associate Professor with tenure in 1995. He was recruited to Vanderbilt University in 1996 where he was promoted to full Professor in 1998. He is currently Professor of Medicine, Cell Biology, and Cancer Biology at the Vanderbilt University Medical Center and Director of the Experimental Therapeutics Program and the Thoracic Oncology Center at the Vanderbilt-Ingram Cancer Center. He is also Director and Principal Investigator of the Vanderbilt Specialized Program of Research Excellence (SPORE) in Lung Cancer and the Strategic Partnering to Evaluate Cancer Signatures UO1 consortium. His research interests, grant support and publications have been focused on lung cancer, and specifically proteomic and expression array signature development, lung cancer genetics, cancer immunotherapy, tumor-associated immunosuppression mechanisms and gene therapy. Recent research directions include molecular profiling of lung cancers and preneoplasias, especially the use of mass spectrometry-based proteomics. He has over 150 peer-reviewed publications and review articles, has served on several NCI grant review panels, including the clinical program project parent committee, and has continuous NCI funding since early in his career. He has served on organizing committees for both ASCO and AACR and is currently Chair of the Lung Biology subcommittee for the Eastern Cooperative Oncology Group, the national SPORE executive committee, the Board of Directors of the International Association for the Study of Lung Cancer (IASLC) and serves on the Board of Scientific Counselors for the NCI.

Fatima CARDOSO, MD

Dr Fatima Cardoso finished medical school in 1992 at the University of Porto, Portugal, and her specialization in medical oncology (board certification) in July 2000 at the Portuguese Institute of Oncology – Porto Center, Portugal. She is also board certified in internal medicine since October 2004. She had two research fellowship periods, one at the Translational Research Unit of the Jules Bordet Institute (Prof. Martine Piccart) in Brussels, Belgium, and another at the Department of Molecular and Cellular Oncology of the MD Anderson Cancer Center, Texas, USA (Prof. Mien-Chie Hung), sponsored by educational grants from the Université Libre de Bruxelles and from the MD Anderson Cancer Center and from the Fonds Jean-Claude Heuson of Belgium, respectively. Since October 2003, she has been an Assistant Professor at the Medical Oncology Clinic of the Jules Bordet Institute, where, besides her clinical work, she is active in the Translational Research Unit and is responsible for phase II–III trials in breast cancer. She is the Scientific Director of the TRANSBIG, daily managing this international research network and, and being the co-Principal Investigator of the MINDACT trial, TRANSBIG's main project.

Her main research interests include biology of breast cancer, prognostic and predictive markers of response to systemic therapy and new anticancer agents. She is an active member of ESMO, ECCO, EORTC and IBCSG, where she is part of several committees. She is also an active member of several other societies such as ASCO, AACR, WICR, EACR. Since 2009, she is the coordinator of the Breast Cancer Program of the European School of Oncology (ESO). She also chairs, with Dr. Eric Winer, the ESO Task Force for the development of international guidelines for metastatic breast cancer. She has been invited to give lectures in numerous national and international meetings, is a member of the faculty of

the FECS/AACR/ASCO Flims Workshop on "Methods in Clinical cancer Research" and of ESO. She is a professor of the Master in Oncology program of the Portuguese Institute of Oncology, University of Porto, Portugal. She is co-editor-in-chief of The Breast Journal, associated editor of EJC and member of the editorial board of several other Journals. She presently has around 230 publications.

She had received several educational and research grants from the European Society of Medical Oncology (ESMO), the Federation of European Cancer Societies (FECS), the Portuguese League Against Cancer, the Portuguese Ministry of Health, the Free University of Brussels, the "Fonds Jean-Claude Heuson", the Fondation Lambeau-Marteau, the Belgian Federation against Cancer, the Breast Cancer Research Foundation, the Susan G. Komen Foundation, and the European Union Framework VI Programme.

Caroline J. CHAPMAN, PhD

Current Position – Associate Professor, Tumour Immunology Group, Division of Surgery, School of Clinical Sciences, University of Nottingham.

The majority of her work in the last eight years has been focussed on the nature of the immune response to recombinant and natural tumour-associated antigens in cancer – with particular reference to breast and lung tumours.

The ultimate aim of this research is the accurate and reproducible detection of specific tumour-associated autoantibodies, leading to the earlier detection, and subsequent improved prognosis, of individual with cancer.

Key Publications in this area are listed below.

Chapman CJ, Murray A, McElveen JE et al. Autoantibodies in Lung Cancer – possibilities for early detection and subsequent cure. Thorax 63:228–33. 2008.

Chapman CJ, Murray A, Chakrabarti J, et al. Autoantibodies in Breast Cancer: their use as an aid to early diagnosis. Annals of Oncology 18: 868–73. 2007.

Parsy CB, Chapman CJ, Barnes AC et al. A two-step method to isolate target recombinant protein from co-purified bacterial contaminant SlyD after immobilised metal affinity chromatography. Journal of Chromatography B 15;853:314–9. 2007.

Robertson,JFR, Chapman CJ, Cheung KL, et al. Autoantibodies in Early Breast Cancer. Journal of Clinical Oncology, 23, 549. 2005.

Storr SJ, Chakrabarti J, Barnes A, Murray A, Chapman CJ, Robertson JFR. Use of autoantibodies in breast cancer screening and diagnosis. Expert Review of Anticancer Therapy, 6: 1215–1223. 2006.

Woodard KW & Chapman CJ Lung cancer – can autoantibodies provide an aid to diagnosis? Expert Opinion on Medical Diagnostics 2008.

Douglas P. CLARK, MD

Dr. Douglas P. Clark is a Professor of Pathology & Oncology at The Johns Hopkins Medical Institutions. He is also Director of the Division of Cytopathology at Johns Hopkins and is a Board-Certified Anatomic Pathologist and Cytopathologist. His current research interests are focused in the area of cancer diagnostics. Dr. Clark's laboratory is interested in the molecular characterization of cellular damage and the discovery of novel biomarkers for cancer. The translational arm of his research laboratory is interested in characterizing molecular alterations in cytologic samples of human tumors and developing molecular biomarkers to guide targeted cancer therapy.

Dr. Clark serves on the editorial advisory boards of Cancer Cytopathology, CytoJournal, and Expert Review of Molecular Diagnostics. Dr. Clark has published over 100 original papers, reports, review articles, abstracts, book chapters and books. Dr. Clark has held national pathology leadership positions, including Scientific Program Chair for the Annual Meeting of the American Society of Cytopathology and Subcommittee Chair for the NCI Thyroid Fine Needle Aspiration State of the Science Conference. Dr. Clark also serves on the Scientific Advisory Board for BD/TriPath Oncology and is a founder of BioMarker Strategies, LLC.

Dr. Clark received his M.D. degree from The Johns Hopkins School of Medicine, Baltimore, Maryland and his B.A. degree in Biochemistry and Molecular Biology from Northwestern University, Evanston, Illinois.

Gary M. CLARK, PhD

Gary M. Clark, Ph.D. is Vice President of Biostatistics & Data Management at Array BioPharma Inc in Boulder, Colorado, USA. He is actively involved in the development of targeted therapies for various cancers. His areas of expertise and interest include the identification and evaluation of prognostic and predictive biomarkers for breast cancer, lung cancer and other solid tumors, and the design and analysis of Phase I, II, III clinical trials of targeted therapies. Prior to joining Array BioPharma in 2008, he was Vice President of Biostatistics & Data Management at OSI Pharmaceuticals, Inc. in Boulder, Colorado where he helped develop and was instrumental in the regulatory approval of a small molecule inhibitor of EGFR tyrosine kinase. Prior to joining OSI Pharmaceuticals in 2002, Dr. Clark served at Baylor College of Medicine in Houston, Texas (1999–2002) as Professor of Medicine and Associate Director of the Breast Center, Director of Tissue Resources, and Director of Informatics. His previous positions included service at the University of Texas Health Science Center at San Antonio, Texas (1980–1999) where he was Professor of Medicine in the Division of Medical Oncology and Director of the Biostatistics, Data Management & Data Processing

Shared Resource of the San Antonio Cancer Institute. Dr. Clark has an extensive list of publications in the area of early drug development and has significantly contributed to the field of biomarkers in breast cancer and other solid tumors. He has been a member of numerous committees of the National Cancer Institute, AACR and ASCO, including several grant review and consensus development panels. He was co-director of the AACR/ASCO Workshop on Methods in Clinical Cancer Research in Vail, Colorado from 1996 to 2000, and co-director of the FECS/AACR/ASCO Workshop on Methods in Clinical Research in Flims, Switzerland from 1999 to 2005.

Robert CLARKE, PhD

Dr Clarke did his undergraduate BSc studies in Biology at the University of Sussex and the Université de Grenoble in France, graduating in 1987.

Following two and half years as a Research Assistant with Professor Potten at the Paterson Institute for Cancer Research, Dr Clarke studied the control of proliferation in the normal and neoplastic human mammary gland for his PhD at The University of Manchester (1995). Subsequently, he undertook post-doctoral training with Dr Liz Anderson in the Clinical Research Department of The Christie, Manchester.

Dr Clarke returned to The University of Manchester as a Cancer Research UK Research Fellow in 2001, becoming a Group Leader in the Division of Cancer Studies at the Paterson Institute for Cancer Research.

He is currently a Senior Lecturer and Breast Cancer Campaign Research Fellow within the School of Cancer and Imaging Sciences in the Paterson Institute for Cancer Research, University of Manchester.

Thomas P. CONRADS, PhD

Thomas P. Conrads, Ph.D., an expert in developing and applying new technologies to characterize proteins and small molecules toward development of new biomarkers for cancer early detection, is Co-Director of the University of Pittsburgh Cancer Institute Cancer Biomarkers Facility and Mass Spectrometry Platform and holds a primary academic appointment as Associate Professor of Pharmacology & Chemical Biology in the University of Pittsburgh School of Medicine with secondary appointments in the Departments of Biomedical Informatics and Medicine.

Dr. Conrads' research program focuses on the development of new chemistry and biology technologies for the characterization of proteomic and metabolomic changes that are associated with clinically relevant questions in cancer biology. The goal of these efforts is to enhance the management of patients with cancer through improved early detection, patient stratification, and monitoring for therapeutic efficacy, outcome, and recurrence.

After receiving his bachelor's degree in biochemistry and biophysics from Washington State University, Dr. Conrads earned his Ph.D. in biochemistry at the Ohio State University. He also completed a postdoctoral fellowship at the Pacific Northwest National Laboratory in Richland, Washington, where he served has a senior staff scientist as well. He has authored and co-authored more than 140 publications in peer-reviewed medical and basic science journals, and currently holds six patents.

Maria Grazia DAIDONE, PhD

Maria Grazia Daidone, Ph.D. is head of the Department of Experimental Oncology and Molecular Medicine of the Fondazione IRCCS – Istituto Nazionale Tumori of Milan, Italy, and she serves as Director of the Research Unit of Translational Research, at the same Department.

She is actively involved in the bio-molecular characterization of human cancers and pre-neoplastic lesions. Her areas of expertise is dealing with investigations on proliferation markers and cytoprotective factors, including telomere-maintaining mechanisms and apoptosis-related factors. Her interest include translational studies in breast, ovarian, head and neck, colorectal cancers, melanoma, and soft tissue sarcomas, with the identification, evaluation and validation of prognostic and predictive biomarkers. With the main aim to translate research information into clinically useful results, she maintains close collaborations with the clinical Departments of her Institute and is currently in charge, with the Head of the Pathology Department, of the development and management of the Frozen Tissue Bank of the Istituto Nazionale Tumori. At a national level, she has been involved in quality control programs for biomarker determination as well as in the proposition of guidelines for the clinical use of biomarkers.

Moreover, her research group is focused on the identification and validation of cancer-related molecular targets, and extends from therapeutically oriented studies, addressed to designing innovative approaches to interfere with cancer cell survival, to optimizing their use in different experimental models (including tumor-initiating cells) and testing new drug delivery systems, to more clinically oriented studies addressed to elucidate the role of the investigated targets on disease progression.

She has been recently nominated Chairperson of the PathoBiology Group (PBG) of the European Organization for Research and Treatment of Cancer (EORTC) and also served as vice-Chairperson of the EORTC Receptor and Biomarker Group before its merging with the Pathology Group into the PBG. Maria Grazia Daidone is a member of the editorial boards of several journals and is a member of national and international Committees for grant review.

Janet E. DANCEY, MD, FRCPC

Dr. Dancey is Program Leader, High Impact Clinical Trials, Ontario Institute for Cancer Research, Director, Translational Research (Clinical) at NCIC Clinical Trials Group and Professor, Department of Oncology, Queen's University. Previously, she was Associate Chief in the Investigational Drug Branch of the Cancer Therapy Evaluation Program of the National Cancer Institute (NCI-US). She completed medical school at the University of Ottawa in 1988 and trained in internal medicine and medical oncology at the University of Toronto. She received certifications in internal medicine and medical oncology from the Royal College of Physicians and Surgeons of Canada in 1992 and 1993 respectively. She has completed research fellowships at the Investigational New Drugs Division of NCIC CTG and at the Institut Gustave Roussy, Villejuif, France. Dr. Dancey has extensive experience in cancer therapeutic and biomarker development. At the NCI she was responsible for identifying areas of therapeutic potential for the agents, initiating and monitoring clinical trials and providing expert advice to NCI senior staff, extramural investigators and pharmaceutical collaborators on scientific and regulatory issues. In addition, she is chair of the Biomarkers Task Force of the Investigational Drugs Steering Committee for CTEP-NCI. She was a member of the Lung Cancer Concept Evaluation Panel, responsible for reviewing, and approving proposals for cooperative group phase 3 studies in lung cancer. She served on the joint ASCO–FDA committee assessing traditional and non-traditional endpoints in lung cancer studies. She was a member of the American Society of Clinical Oncology Program Committee 2001–2002, and 2007–8, and served as Chair of the Clinical Pharmacology Subcommittee for the 2002, Track Leader for the Developmental Therapeutics – Molecular Therapeutics subcommittee in of the 2007–8 ASCO Program Committee. She was a member of the Scientific Committee of the AACR–NCI–EORTC Molecular Targets 2003 and 2005 Meetings and the co-chair of the Scientific Committee for the 2004 meeting. Dr. Dancey has presented at national and international oncology meetings and has been an invited speaker at other cancer centres and CME events. She is a member of the Editorial Board of PDQ. She is the author or co-author of over 100 publications, 90 abstracts presented at international meetings in oncology and 15 book chapters in the areas of oncology therapeutics development, clinical trial methodology patient reported outcomes research, and treatments for lung and gastrointestinal malignancies.

Romano DANESI, MD, PhD

Dr. Romano Danesi graduated in Medicine in 1983; then he received his Ph.D. degree in pharmacology and chemotherapy at the Superior School S. Anna, Pisa (1984–88), and his board certifications in diseases of the respiratory apparatus (1988), clinical pharmacology (2001) and medical oncology (2006) at the University of Pisa, Italy. He was appointed assistant professor of Pharmacology in 1991 at the Superior School S. Anna, Pisa; he was associate professor of Chemotherapy from 1998 to 2005 and then full professor of Pharmacology at the University of Pisa since 2005. He was awarded fellowships of the Italian Association for Cancer Research (AIRC), Italian Foundation for Cancer Research (FIRC), European Organization for Research and Treatment of Cancer (EORTC) and U.S. Public Health Service – Exchange Training Program, to work in the Clinical pharmacology Branch, NCI, Bethesda, MD (USA) (1998–90) and as Assistant professor of Hematology/Oncology in the Division of Hematology-Oncology of the University of Virginia at Charlottesville (USA), (1993–94). He was special volunteer in the Molecular Pharmacology Section, Cancer Therapeutics Branch, Center for Cancer Research, NCI, Bethesda, MD (August 2003–2008). He is visiting professor at Yale University Cancer Center (New Haven, CT) and at the National Cancer Institute, Bethesda, MD). Since 1985, he published 180 full papers in international journals, including Journal of Clinical Oncology, Clinical Pharmacology and Therapeutics, Molecular Pharmacology, Clinical Cancer Research, Cancer Research, Trends in Pharmacological Sciences and Pharmacological Reviews. Dr. Danesi serves as a reviewer of international journals, including Cancer Research, Clinical Cancer Research, Journal of Clinical Investigation, European Journal of Cancer, Biochemical Pharmacology, Journal of Chromatography B, Oncology, Critical Reviews in Oncology/Hematology, Pharmacological Research, FASEB Journal and Cancer Chemotherapy and Pharmacology. Finally, he is member of the Grant Review Committee of the European Commission (6th Framework Programme, 2002–06 LIFESCIHEALTH), Swiss Group for Clinical Cancer Research (SAKK), the Grant Agency of the Czěck Republic (GACR), the Italian National Research Council (CNR) and the Italian Ministry of University (MIUR).

Elizabeth A. EISENHAUER, MD, FRCPC

Elizabeth Eisenhauer is Director of the NCIC Clinical Trials Group Investigational New Drug Program based at Queen's University in Kingston ON Canada. She also holds an appointment as a Professor in the Department of Oncology at Queen's. She obtained her MD at Queen's and went on to train in Internal Medicine and Hematology, obtaining fellowships from the Royal College of Physicians and Surgeons (Canada) in 1980 and 1981.

Her main research interest and activity is the coordination of phase I and II trials of a wide range of novel anticancer

agents through the NCIC CTG network of investigators. She has served on numerous national and international committees in the area of oncology research.
From June 2006-February 2009 she was President of the National Cancer Institute of Canada. She has served on the Board of the American Society of Clinical Oncology, the Canadian Cancer Society, the Ontario Cancer Research Institute, the Canadian Institutes of Health Research Institute of Cancer Research is a member of the Scientific Audit Committee of the European Organization for Research and Treatment of Cancer. In 2008 she became co-Chair of the Canadian Cancer Research Alliance and Chair of the Research Action Group of the Canadian Partnership Against Cancer.

Phillip G. FEBBO, MD
Dr. Febbo uses genomic technologies and defined genetic and/or chemical perturbations to investigate prostate cancer biology and anticipate response to therapy in established prostate cancer cell lines, genetically-defined cell lines, prostate cancer mouse models, and clinical prostate cancer specimens. Some examples of discoveries from his work include being the first to publish a multi-gene expression-based predictor of prostate cancer recurrence after surgery, discovering decreased Hif pathway activity following mTOR inhibition, and identifying mechanisms of resistance associated with androgen ablation, docetaxel, imatinib mesylate, and mTOR inhibition. A unique aspect of his work has been a consistent focus on the incorporation of expression analysis into clinical trials. He has worked to create "learning loops" for prostate cancer clinical trials where the analysis of samples from one trial informs the design and implementation of subsequent clinical trials. Most recently, he is prospectively validating predictive, expression-based signatures for docetaxel, mTOR inhibition, and androgen receptor (AR) activity in metastatic prostate cancer. His trial using a microarray-based signature of AR activity to determine therapy for men with metastatic prostate cancer will be the first trial to personalized care for men with prostate cancer based upon a molecular phenotype of their specific tumor and is emblematic of how he aims to improve and personalize care for the men diagnosed with this disease.
Dr. Febbo received his B.A. from Dartmouth College and his M.D. from University of California, San Francisco. He completed Internship and Residency in Internal Medicine at the Brigham and Women's Hospital and his Fellowship in Medical Oncology at the Dana Farber Cancer Institute both in Boston, MA. While completing his clinical training in Oncology, Dr. Febbo completed a post-doctoral fellowship with Dr. Todd Golub at the Whitehead Institute Center for Genomic Research (now the Broad Institute) before taking his current position at Duke University at the Institute for Genome Sciences & Policy within the Departments of Medicine and Molecular Genetics and Microbiology. He is an Associate Professor of Medicine, Member of the Cancer Center, Vice-Chair of the Genitourinary Committee of the Cancer and Leukemia Group B (CALGB), Chair of the Biospecimen and Correlative Science Advisory Committee of CALGB, a member of ASCO Cancer Research Committee, and a member of the American Society of Clinical Investigation.

Tanja FEHM, MD, PhD
Academic education and professional experience: 1993–1998: Medical School University of Erlangen-Nürnberg, Germany. 1998–1999: Resident, Department of Gynecology and Obstetrics, Medical School University of Erlangen-Nürnberg, Germany. 1999–2001: Postdoctoral fellow in the laboratory of Dr. Vitetta/Dr. Uhr, Cancer Immunobiology Center, UT Southwestern, Medical School, USA. 2000: Visiting Scientist in the lab of Dr. Ried, NIH, USA. Since 2001: Adjacent assistant professor, Cancer Immunobiology Center, UT Southwestern, Medical School. 01–09/2002: Resident, Department of Gynecology and Obstetrics, Medical School University of Erlangen-Nürnberg, Germany. Since 09/2002: Resident, Department of Gynecology and Obstetrics, Medical School University of Tübingen, Germany. 01/2004: Leader of the research group "minimal residual disease" and the research group "tumor progression". Since 7/2005: Board certified gynecologist. Since 11/2005: Associate professor for Gynecological Oncology. Since 1/2007: Full professor for gynecological oncology and translational research, Dept. Gynecology and Obstetrics, Tuebingen, Germany. Since 07/2008: Spokesman of the Interdisciplinary Center of Gynecological Oncology of the Cancer Comprehensive Center, Tuebingen.
Societies: Society of Statistics and Biomedical research (GMDS), German Society of Obstetrics and Gynecology, German Society of Senology, American Society of Clinical Oncology, European Society of Gynecological Oncology, German Cancer Society.
Research topics: Shedding HER2 protein in breast cancer, tumor cells and their microenvironment, detection of disseminated tumor cells in blood, bone marrow and sentinel lymph node, phenotypic characterization of disseminated tumor cells to study their biological role, identification of gene signatures predicting therapy response to adjuvant and neoadjuvant chemotherapy.

Patrick FLAMEN, MD, PhD
Dr Patrick Flamen is the head of the Nuclear Medicine department of the Institut Bordet in Brussels. He obtained his PhD degree at the University of Leuven in 2001 were

he worked on the use of FDG PET imaging in digestive oncology, mainly focusing on metabolic response assessment of neo-adjuvant chemoradiation in esophageal cancer. Presently, he is involved in multiple research projects on the use of molecular imaging techniques, with hybrid PET(CT) technology, for predictive or prognostic biomarking in oncology.

Herbert A. FRITSCHE, PhD

Dr. Herbert Fritsche is Professor and Chief of Clinical Chemistry at M. D. Anderson Cancer Center. Dr Fritsche directs the clinical chemistry testing operations for the MD Anderson Hospital and Outpatient Clinics, and conducts an active research program in the development and validation of cancer diagnostics. He served as National President of the Clinical Ligand Assay Society, and he is a member of the editorial board of six journals, a Fellow in the National Academy of Clinical Biochemistry (NACB), a member of the Tumor Marker Expert Panel (American Society of Clinical Oncology), the Tumor Marker Guidelines Committee for (NACB), and the Technology Expert Panel for Blue Cross Blue Shield. He has lectured at many international meetings and has published more than 180 manuscripts and 30 book chapters in the field of cancer diagnostics. He is a member of the scientific advisory boards for seven companies, holds four patents and two patent applications, is the co-author of a textbook on Tumor Markers, published by AACC press, and he is the Meeting Director of a Biennial Conference on Cancer Diagnostics sponsored by the M. D. Anderson Cancer Center.

David R. GANDARA, MD

David R. Gandara, MD, professor of medicine at the University of California, Davis School of Medicine is Associate Director of Clinical Research and Director of Thoracic Oncology at the University of California, Davis Cancer Center. He is a diplomat of the American Board of Internal Medicine specializing in Medical Oncology. He is currently principal investigator for a number of research projects in lung cancer, pharmacology trials at various phases, and Southwest Oncology Group trials. He is the principal investigator for a National Cancer Institute award to the California Cancer Consortium for Early Therapeutic Trials of New Anti-Cancer Agents. He is chair of the Southwest Oncology Group (SWOG) Lung Committee, and a member and prior co-chair of the NCI-directed Investigational Drug Steering Committee. He has written and published over 300 articles, book chapters, abstracts and editorials. He is editor-in-chief of Clinical Lung Cancer, serves on the editorial board of four oncology journals, and is a manuscript reviewer for eight additional journals. He has served as the President-Elect and is the incoming President for the International Association for the Study of Lung Cancer (IASLC) and serves on the board of directors. He is a prior board member and secretary-treasurer of the American Society for Clinical Oncology (ASCO). He also is chair of the NCI-directed Lung Correlative Science Committee. After receiving his medical degree from the University of Texas Medical Branch in Galveston, Dr. Gandara was an intern and resident at the Madigan Army Medical Center in Tacoma and a fellow at the Letterman Army Medical Center Presidio of San Francisco.

Professor Nadia HARBECK, MD

Professor Nadia Harbeck is Head of the Breast Center at the University of Cologne, Germany. She also heads the Oncological Therapy Unit and the Clinical Trials Unit at the University Department of Obstetrics and Gynaecology (OB&GYN) in Cologne. Until March 2009, she was Associate Professor of OB&GYN at Technical University of Munich (Germany), responsible for breast cancer systemic therapy, and clinical research.

Professor Harbeck is a member of the expert panel issuing the yearly updated evidence-based AGO Guidelines for breast cancer therapy in Germany (www.ago-online.de). In addition, she is an EORTC executive board member, a steering committee member of the EORTC PathoBiology Group and the AGO translational research commission (TRAFO) and a member of numerous other professional organisations (e.g. ASCO, ESMO, AACR).

Professor Harbeck is principal investigator or steering committee member of numerous national and international clinical breast cancer trials, with a recent focus on trials using novel targeted compounds. She is member of the international TransHERA and co-chair of TransALTTO committee. Her translational research focuses on prognostic and predictive factors in breast cancer (e.g. uPA/PAI–1, PITX2, YB–1 etc.) and other solid tumors. Regarding the uPA/PAI–1 system, she helped to validate these factors at highest level of evidence in breast cancer and is co-chair of the second multicenter trial (NNBC–3) using uPA/PAI–1 for clinical decision making in node-negative breast cancer (n = 4,150).

Professor Harbeck has authored >190 papers in peer-reviewed journals (cum. IF> 650) and, in addition to serving on the editorial boards (e.g. Journal of Clinical Oncology) or as a reviewer for several scientific journals and grant-giving agencies (e.g. German Cancer Aid), she is Coordinating Editor-in-Chief of Breast Care. Moreover, she serves on the organizing committees for numerous national and international clinical and translational cancer meetings. For her clinical translational research, she has received numerous awards, including a 2001 AACR award, the 2001 ASCO Fellowship Merit Award and

the 2002 AGO Schmidt-Matthiesen Award. She was also invited to give the Emmanuel van der Schueren Lecture at the 6th European Breast Cancer Conference (EBCC, Berlin) 2008 and the Opening Lecture at IBCM–2, Sarajevo 2009.

Susan G. HILSENBECK, PhD

Susan G. Hilsenbeck, Ph.D., has a Ph.D. in Applied Statistics. She joined Baylor College of Medicine (Houston, TX) in 1999 as a founding member of the Breast Center and is a Professor of Medicine (Tenured). Dr. Hilsenbeck leads the Biostatistics and Informatics Group in the Breast Center and the Biostatistics Shared Resource in the Dan L. Duncan Cancer Center. She is a Vice Chair of the Baylor College of Medicine Institutional Review Board, has served on numerous NIH grant review panels, and is currently a member of the Cancer Biomarkers Study Section.

She collaborates as the statistician on a number of clinical trials and is the leader of statistical shared resources for several multi-project grants. She has research interests in the identification and validation of prognostic and predictive factors in Breast Cancer, and in trials of targeted therapy and the design and analysis of trials for predictive markers, and she has over 200 publications in these research areas.

Dr. Hilsenbeck is a member of several committees of NCI, AACR, and ASCO, and in 2008 she became a member of the ASA Board of Directors. She helped create and has been a faculty member of the AACR "Biostatistics Workshop" in Sonoma, California since 2008. She has been on the faculty of the EORTC–AACR–ASCO "Methods in Clinical Cancer Research Workshop" in Flims, Switzerland since 2007, and from 1998–2007 as a faculty member for the AACR/ASCO "Methods in Clinical Cancer Research Workshop" in Vail, Colorado.

Stuart HOGARTH

Stuart Hogarth is a member of the Global Biopolitics Research Group at the Centre for Biomedicine and Society at King's College London, where he is currently working on a comparative analysis of the innovation strategies employed by European states to support the field of regenerative medicine. His broader research interests include the innovation processes in the drugs and diagnostics industries and the regulatory issues emerging from novel healthcare technologies. Stuart has published a number of articles and policy papers on the regulation of genetic tests, with a particular focus on pharmacogenetics and susceptibility testing. He has produced two policy reports for Health Canada on this topic as well as briefings for the UK Human Genetics Commission and the European Commission, and has received an FDA Leveraging/Collaboration Award for his work in this area. Stuart has been on the organising committee for international meetings on genetic testing in the United States and Japan and continues to play a role in the development of regulation in this area, most recently as a member of the UK working group which is developing a Common Framework of Principles for direct-to-consumer genetic testing.

J. Milburn JESSUP, MD

J. Milburn Jessup, MD is a surgical oncologist who joined the Cancer Diagnosis Program at the National Cancer Institute as Chief of the Diagnostics Evaluation Branch three years ago after more than 25 years of practice in the multidisciplinary treatment of GI and breast cancer as well as melanoma and soft tissue and skeletal sarcomas in several different academic settings. He also led a research effort studying the mechanisms that underpin hepatic metastasis by human colorectal carcinoma and identified roles for the marker Carcinoembryonic Antigen in modulating inflammatory responses and promoting metastasis. As an Adjunct Investigator in the Laboratory of Experimental Carcinogenesis of the Center for Cancer Research, NCI he focuses on cancer stem cells in colorectal carcinoma that give rise to liver metastases. Currently he is the Chair of the American Joint Committee on Cancer Hindgut Task Force and a member of the College of American Pathologists GI Cancer Checklist committee.

Bruce E. JOHNSON, MD

Bruce E. Johnson, MD is Director of the Lowe Center for Thoracic Oncology at Dana-Farber Cancer Institute and Brigham and Women's Hospital, and Professor of Medicine at Harvard Medical School. He is the leader of the Dana-Farber/Harvard Cancer Center Lung Cancer Program and the Principal Investigator of the Dana-Farber/Harvard Cancer Center Specialized Program of Research Excellence (SPORE) in Lung Cancer. Dr. Johnson's laboratory-based research is devoted to testing novel therapeutic agents for their efficacy against lung cancer and other thoracic malignancies. Under his leadership, the Lowe Center for Thoracic Oncology has recently launched the "genomics initiative", with the goal to first, expand the percentage of patients undergoing genomic characterization and second, to put more patients on trials with genomic eligibility criteria.

He is currently chair of the biology subcommittee to the External Scientific Committee for the NCI National Human Genome Research Institute Pilot Project Characterizing Cancer Genomes. He serves as Senior Editor for Clinical Cancer Research and is on the Editorial Board for International Journal of Oncology and

Journal of Clinical Oncology. From 2001 to 2005, Dr. Johnson served as Chair of the Small Cell Lung Cancer Guidelines Committee for the National Comprehensive Cancer Network (NCCN). He recently was elected to the ASCO Board of Directors and received the ASCO Cancer Foundation's Translational Research Professorship. He is currently one of four project leaders of the World Health Organization's Pathology Panel, who are redefining adenocarcinoma of the lung by integrating the different genetic markers into different types of lung cancer.

Dr. Johnson received his MD from the University of Minnesota and did his postgraduate training at the University of Chicago and the National Cancer Institute. He came to the Lowe Center in 1998, after serving for six years as the head of the Lung Cancer Biology section of the NCI's Medicine Branch.

Paula KIM

Paula Kim is a long-time patient and research advocate and proponent of multidisciplinary approaches to healthcare and clinical research. She is well-known for her ability to bridge complex gaps to harmonize related but disparate efforts, and she currently serves as CEO of Translating Research Across Communities (TRAC), a global healthcare consultancy. Paula enjoys an active approach to empowering research by raising awareness and connecting the vital links between research, participation, dissemination of information, and support. Her motivation came as a caregiver for her dad who died from pancreatic cancer just seventy five days after diagnosis.

Paula's international interests include helping to establish a national cancer plan in the Croatia-United States Oncology Task Force, strengthening dialogue for national biobanking systems in Ireland and South Korea, and assisting the development of the first cancer patient advocacy organization in Japan with mentoring to their leadership. Community efforts include the National Accreditation Program for Breast Centers (NAPBC), C-Change, National Coalition for Cancer Research, National Pancreas Foundation, and serving as an external advisor to research and advocacy programs in the United States and abroad.

Paula has regularly contributed to a number of governmental cancer and health initiatives including the National Institutes of Health, National Cancer Institute (NCI) Biospecimen Coordinating Committee, NCI Board of Scientific Advisors, Directors Consumer Liaison Group, Clinical Trials Gastrointestinal Steering Committee, Patient Advocacy Steering Committee, CaBIG, and the FDA Patient Consultant Liaison Program.

In 1999, she was a co-founder and served as the founding Chairman of the Pancreatic Cancer Action Network, Inc. (PanCAN), the disease's first and, at that time, only national patient advocacy organization, later serving as President through 2004. She developed and led the creation of the first disease specific research map for pancreas cancer; the PALS-Patient and Liaison Services program-a novel patient information navigation and clinical trials screening service; and Team Hope, the grassroots effort that helped to raise awareness and research funding to unprecedented levels in the United States.

Elise C. KOHN, MD

Head, Molecular Signaling Section and Medical Ovarian Cancer Clinic, Medical Oncology Branch, Center for Cancer Research, National Cancer Institute.

Dr. Kohn, a medical oncologist and laboratory scientist, has a primary interest in treatment of recurrent ovarian cancer through targeting signaling events in the microenvironment. She has developed approaches to allow her to measure endpoints in the microenvironment to confirm that the events targeted in her clinical trials and in her laboratory are affected. Dr. Kohn has pioneered using proteomic arrays as tools to dissect signaling events in serially obtained tissue biopsies from patients on her trials. Her therapeutic and research interests lie in modulating the interaction of the tumor and its stroma through antiangiogenic and signal inhibitory combination therapies. In addition to her laboratory and clinical work, Dr. Kohn is an active mentor for students of all levels and medical oncology fellows and postdoctoral fellows. She has developed international collaborations for science and training. Dr. Kohn serves on the Department of Defense Ovarian Cancer Research Program, the Gynecologic Cancer Steering Committee, and is Co-Chair of the Breast and Gynecologic Malignancies Faculty of the Center for Cancer Research, NCI. She is a protocol PI in Gynecologic Oncology Group and a member of its ovarian cancer committee and developmental therapeutics committees. In 2006, Dr. Kohn was the recipient of the Ovarian Cancer National Alliance's Rosalind Franklin Excellence in Ovarian Cancer Research Award and the NIH Director's Merit Award, and in 2007 she received both Diversity and Mentoring Awards. Dr. Kohn was elected a Fellow of the American Association for the Advancement of Science in 2002. She has been recognized for her clinical and scientific mentorship.

Heinz-Josef LENZ, MD, FACP

Heinz-Josef Lenz, MD, FACP, is Professor of Medicine and Professor of Preventive Medicine in the Division of Medical Oncology at Keck School of Medicine at the University of Southern California (USC), USA. He is Associate Director, Clinical Research, Co-Director of the Colorectal Center and the Gastrointestinal Oncology Program, as well as being Scientific Director of the

Cancer Genetics Unit at USC/Norris Comprehensive Cancer Center in Los Angeles, California.

Dr Lenz received his medical degree from Johannes-Gutenberg Universität in Mainz, Germany, in 1985. He completed a residency in hematology and oncology at the University Hospital Tübingen in Germany, a clerkship in oncology at George Washington University in Washington, DC, and a clerkship in hematology at the Beth Israel Hospital of Harvard Medical School in Boston, Massachusetts. He served subsequent fellowships in biochemistry and molecular biology at the USC/Norris Comprehensive Cancer Center.

An active researcher, Dr Lenz focuses on topics including the regulation of gene expression involved in drug resistance, patients at high risk of developing colorectal cancer, determination of carcinogenesis and methods of early detection of these cancers. He is a member of several professional societies, and serves on the national advisory boards of a number of professional organizations. Dr Lenz is the author of numerous peer-reviewed publications and invited papers, reviews, and editorials. In addition to having a National Cancer Institute-funded laboratory, he is a recipient of the ASCO Young Investigator Award, the ASCO Career Development Award, a NCI MidCareer Development Award and the STOP Cancer Career Development Award. He is the Co-Chair of the SWOG GI Committee, and the Chair of the Correlative Science within the GI Committee. He is member of the NCI Steering Committee and Member of the Intergroup Correlative Science Group. He is PI of a U10, U01 and R01. His laboratory was the first to identify germline polymorphisms to predict outcome and toxicity to chemotherapy.

Geoffrey LIU, MD, MSc, FRCPC

Dr. Liu is the Alan B. Brown Chair in Molecular Genomics at Princess Margaret Hospital/Ontario Cancer Institute and University of Toronto. He also holds the only joint provincial Cancer Care Ontario Chair in Experimental Therapeutics and Population Studies. Graduating Summe Cum Laude from University of Toronto, Dr. Liu completed internal medicine training at the University of Toronto and Medical Oncology training at Dana Farber Harvarc Cancer Center. In 2001 he became a Doris Duke Clinician Scientist in solid tumour molecular epidemiology at Massachusetts General Hospital. He returned to the University of Toronto in 2006, where he holds cross-appointments at both the Harvard and Dalla Lana Schools of Public Health. Currently he has over two dozen active pharmacogenetic and molecular epidemiologic studies with the National Cancer Institute of Canada Clinical Trials Group, with other cooperative groups, and with industry. Funded with over 6 million dollars of peer-reviewed grants in 2009 by the NIH/NCI, Canadian Cancer Society, Canadian Institute for Health Research, Ontario Institute of Cancer Research, Dr. Liu's laboratory focuses on pharmacogenetic epidemiologic studies in solid tumours designed to identify and validate predictive and prognostic pharmacogenetic biomarkers. In 2008 he won the National Cancer Institute of Canada William Rawls Proze for contributions that have led to important advances in cancer control within the past decade. He is also co-chair of the International Society of Pharmacoepidemiology Special Interest Group in Molecular Epidemiology and Pharmacogenetics, where he focuses on the education and training of young pharmacogenetic epidemiologists.

Tracy LIVELY, PhD

Dr. Tracy Lively joined the NIH in 1996 as a program director in the Cancer Diagnosis Program of the National Cancer Institute. Prior to coming to the NIH she had been an assistant professor in the Division of Biomedical Sciences at the University of California, Riverside, and had completed post-doctoral fellowships in cancer biology and human genetics. As a program director, and later as Associate Chief of the Diagnostics Research Branch of the Cancer Diagnosis Program, Dr. Lively has been responsible for the scientific oversight of a portfolio of investigator-initiated research grants. She has also developed and implemented targeted research initiatives for exploratory research, for technology development and for patient-oriented research in cancer diagnostics. She reviews the correlative science aspects of protocols for NCI's clinical trials program. She also organizes scientific meetings and working groups with investigators outside the NIH.

Florian LORDICK, MD, PhD

Department of Medical Oncology and Hematology, Clinic Brunswick.

Medical training at the universities of Regensburg, Munich and Lausanne (1987–1993). Internship and Residency in Munich. Assistant Medical Director (Medical Oncology) at Klinikum rechts der Isar, Technical University of Munich, Germany from 2002–2007. July 2007 – June 2009 at the National Center for Tumor Diseases, University of Heidelberg, Germany. Since June 2009 Head of the Department of Medical Oncology and Hematology at the Clinic Brunswick, Hannover Medical School.

Member of the Board of Directors of the German Arbeitsgemeinschaft Internistische Onkologie (AIO). Member of the Board of the European Organization of Research and Treatment of Cancer (EORTC) GI Tract Cancer Study Group. Member of the Faculty of the European School of Medical Oncology (ESMO) GI Tract Cancer Group.

Scientific focus: Multimodal treatment of gastrointestinal cancer, molecular imaging, response prediction.

Philip C. MACK, PhD

Dr. Mack received his B.A. in Biochemistry and Molecular Biology from University of California, Santa Cruz, California in 1991. He then attended the University of California Davis where he received his Ph.D. in 1997. He did his post-doctoral fellowship training at the University of California Davis under Dr. David Gandara and was recruited to the Division of Hematology and Oncology. Dr. Mack is currently an Associate Adjunct Professor of Medicine and the co-Director of the UC Davis Cancer Center Clinical Molecular Pharmacology Shared Resource, co-Director of the tissue repository for the California Cancer Consortium, and Associate Chair of the Southwest Oncology Group (SWOG) Lung Translational Sciences Subcommittee. He conducts molecular biology and molecular pharmacology studies for the UC Davis Cancer Center, the California Cancer Consortium, and SWOG. For the past ten years, Dr. Mack has conducted basic and translational research, with an emphasis on lung cancer. His investigations include molecular and cellular effects of novel anticancer agents in lung cancer models.

Lisa M. McSHANE, PhD

Lisa M. McShane, Ph.D. is a mathematical statistician in the Biometric Research Branch at the National Cancer Institute (NCI). After receiving her Ph.D. in Statistics from Cornell University, she spent a few years as a statistician at the National Institute of Neurological Disorders and Stroke, and then she joined the NCI. Dr. McShane has served as a statistical advisor to the Cancer Diagnosis Program and Cancer Therapy Evaluation Program on matters relating to use of tumor markers for prognosis, prediction, and disease-monitoring. She is also statistical advisor to the NCI Cooperative Breast Cancer Tissue Resource and a member of the NCI Program for the Assessment of Clinical Cancer Tests (PACCT) Strategy Group. She is a co-author of the REMARK guidelines for standardization of reporting of tumor marker prognostic studies. She is a member of the American Statistical Association and International Biometric Society.

Dr. McShane's statistical interests and publications have covered a diverse set of topics including statistical methods for the analysis of high-dimensional genomic data, multiple comparisons methods, surrogate endpoints, measurement error adjustment methods, statistical methods for laboratory assay quality control, and spatial statistics. She has been statistical coauthor on numerous biomedical papers covering topics including gene expression patterns in breast and colon cancer, colorectal epithelial cell proliferation, serum markers in prostate cancer, molecular characterization of ovarian tumors, Parkinson's disease, motor control disorders, stroke, and Creutzfeldt-Jakob disease. She is co-author of a book "Statistical Design and Analysis of DNA Microarray Investigations" (Springer, 2004).

Margaret MOONEY, MD, MBA

Dr. Mooney is the Chief of the Clinical Investigations Branch in the Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis, at the US National Cancer Institute (NCI), National Institutes of Health (NIH). She is currently also Head of Gastrointestinal and Neuroendocrine Cancer Therapeutics in the Clinical Investigations Branch. She was formerly the Interim Director of the Office of Evidence-Based Surgery at the American College of Surgeons in Chicago, Illinois. She received her medical degree from the University of Chicago Pritzker School of Medicine in Chicago and her general surgical training at the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. She received board certification in surgery in 1997. She completed her Surgical Oncology fellowship training at the Roswell Park Cancer Institute in Buffalo, New York, where she was also a research fellow in the Department of Cancer Control and Epidemiology. Dr. Mooney also holds a Masters of Science degree in Management from the Massachusetts Institute of Technology in Cambridge, Massachusetts.

Dr. Mooney joined the US National Cancer Institute in 2002 as Head of Gastrointestinal and Neuroendocrine Cancer Therapeutics in the Clinical Investigations Branch and was appointed Chief of the Clinical Investigations Branch in May 2009. As Chief of the Clinical Investigations Branch, she is responsible for the direction of the NIH Clinical Trials Cooperative Group Program. This program performs nearly all the phase III cancer treatment trials sponsored by NCI and is a primary vehicle for conducting large, definitive, practice-changing clinical trials. As branch chief, Dr. Mooney supervises a staff that collectively oversees, reviews, and coordinates more than 100 active Phase III treatment trials in various cancer types. As Head of GI and Neuroendocrine Cancer Therapeutics, Dr. Mooney is responsible for the evaluation, coordination, implementation, and conduct of NCI-sponsored Phase III treatment trials in gastrointestinal malignancies including colorectal, esophageal, gastric, pancreatic, other less common GI tumor types, neuroendocrine malignancies as well as surgical trials and multi-modality studies in which surgery is a significant component. Her responsibilities include identifying areas of therapeutic potential for the Phase II trial evaluation of treatment strategies and new investigational agents in GI and neuroendocrine malignancies as well as the research plans preparatory to Phase III studies (e.g., Phase I, Phase II, pilot, and laboratory-translational trials).

Dr. Mooney's achievements have been recognized by six NIH Merit Awards.

Catherine Adell O'BRIEN, MD, FRCSC

Catherine O'Brien is a new Assistant Professor in the Dept of Surgery at University Health Network and a clinician-scientist at the Ontario Cancer Institute. She obtained her MD in 1998 from Queen's University in Kingston, Ontario and completed a general surgery residency at the University of Western Ontario (1998–2003). Following the completion of residency she undertook fellowship training at the University of Toronto in surgical oncology, specializing in gastrointestinal malginancies. During this time she commenced a PhD under the supervision of Dr. John Dick studying cancer stem cells in colon cancer. This work lead to the first identification of human colon cancer stem cells. She has particular interest in utilizing knowledge of the biology and pathways that regulate colon cancer stem cells in translational medicine.

Godefridus J. PETERS, PhD

Professor Godefridus (Frits) Peters is head of the Laboratory Medical Oncology of the VU University Medical Center (VUmc) in Amsterdam (the Netherlands). He studied biochemistry and did his Ph.D. at the University of Nijmegen and did a post-doc at the Netherlands Cancer Institute. His major research interest is pharmacology of anticancer agents, with emphasis on antimetabolites, antifolates, platinum analogs, taxanes and more recently anti-signalling agents. His group was one of the first to describe the prognostic role of thymidylate synthase (TS) in the efficacy of 5-fluorouracil, which subsequently led to the first study to use TS to tailor treatment; selection of patients based on gene expression increased response rate 2-fold. His group described several self-potentiating actions of gemcitabine and was the first to describe the synergism between cisplatin and gemcitabine, now a standard combination in the treatment of non-small cell lung cancer. Current research on drug resistance focuses on the expression and localization of various multidrug-resistance associated proteins (MRPs) and breast cancer associated resistance protein (BCRP), the role of genetic polymorphisms in drug metabolism, gene expression arrays, and DNA arrays using Comparative Genomic Hybridisation. Regulation of gene expression (methylation) and functional aspects (phosphorylation) of drug metabolising enzymes are also studied in order to use them as predictive markers in tailored therapy.

Prof. Peters was/is member of 14 editorial boards and edited the proceedings of several meetings on chemotherapy and translational research. He (co)-organized several Gene to Cure meetings in Amsterdam (on colon, pancreatic and esophageal cancer), two EORTC-PAMM meetings (1999, 2009), a meeting on Chemotherapy of Colon Cancer, on Folates and Pteridines (2005), and the International meeting on Purine and Pyrimidine Metabolism (2003), and was president of that society. Since 2009 he is chair of the EORTC-Pharmacology and Molecular Mechanisms Group

Prof. Peters supervise(d) 23 Ph.D students and is chair of the examination committee of the international (top)master oncology of the VUmc. Prof. Peters has authored/co-authored >300 refereed papers and 165 papers/chapters in books and congress proceedings.

Jeremy N. RICH, MD

Dr. Jeremy N. Rich received his M.D. from Duke University School of Medicine and completed residency training in Internal Medicine (Internship) and Neurology at The Johns Hopkins Hospital and a Neuro-Oncology fellowship at Duke University Hospital. He was appointed to faculty at Duke University Medical Center and became an Associate Professor with Tenure in the Departments of Medicine, Surgery, and Pharmacology and Cancer Biology. He has been recently appointed as inaugural Chair of the Department of Stem Cell Biology and Regenerative Medicine at the Cleveland Clinic, Staff in the Department of Neurology and the Taussig Cancer Center at the Cleveland Clinic, and co-Director of the Center for Stem Cell and Regenerative Medicine. His research is primarily focused on malignant brain tumor biology with interrogation of signal transduction pathways involved in tumor malignancy and the development of targeted therapies with a focus on stem cell biology in brain cancer. His laboratory demonstrated that cancer stem cells contribute to radiation resistance and promote tumor angiogenesis. More recently his laboratory has identified specific molecular targets essential for brain tumor stem cell self renewal and tumor growth. He has received a number of awards, including being named Sidney Kimmel Foundation for Cancer Research Translational Science Fellow, Damon Runyon-Lilly Clinical Investigator, and the Preuss Award for Clinical Neuro-Oncology as well as election to the American Society for Clinical Investigation (ASCI).

David L. RIMM, MD, PhD

Dr. David Rimm, is a Professor in the Department of Pathology at the Yale University School of Medicine. He completed an MD-PhD at Johns Hopkins University Medical School followed by a Pathology Residency at Yale and a Cytopathology Fellowship at the Medical College of Virginia. He is board certified in Anatomic Pathology and Cytopathology. At Yale since 1994, Dr. Rimm is the Director of Yale Pathology Tissue Services and the Yale Tissue Microarray Facility. He is also the Director of Medical Studies for Pathology. His lab group (15 researchers) focuses on quantitative pathology using the AQUA® technology invented in his lab with projects

related to predicting response to therapy in breast cancer and predicting recurrence or metastasis in melanoma and lung cancer. He also has a group working on c-Met tyrosine kinase and group working on spectral/spatial imaging for diagnostics in cytology. He is currently supported by 9 grants from both public and private sources. He serves as a reviewer for the NIH and was a charter member of the Cancer Biomarkers Study Section. He is an editorial board member for 7 pathology journals and a member of the pathology committee for CALGB, TransALLTO and TEACH (cooperative groups or therapeutic clinical trials). He is an author of over 180 peer-reviewed papers and 6 patents and is the scientific co-founder of HistoRx, a digital pathology company and Metamark Genetics, a prognostic determinant company.

Larry RUBINSTEIN, PhD

Larry Rubinstein received a Ph.D. in math/stat from the U of MD (1978). He has been in the Biometrics Research Branch, NCI since 1985. He has published in a variety of areas relating to both clinical and pre-clinical studies. He defined methods for determining the required sample size in phase 3 studies (1). He has been involved in developing new designs for phase 0 trials (10) and phase 1 trials (5) and defining appropriate designs for phase 2 trials (9). He was involved with establishing and updating RECIST response criteria (6,11), and participated in a 10-year review of phase 1 trial risks and benefits (8). He was responsible for statistical analyses for the in-vitro assay used in the NCI human tumor cell line screen (3), as well as statistical analyses that determined the degree of correlation among in-vitro and in-vivo results, for that screen, and phase 2 clinical results (7). He participated in the development of the in-vitro assay analysis tools used at the NCI (2,4). His current responsibilities involve primary statistical review and advising capacities on 100-200 clinical studies per year, as well as service on 2 data monitoring committees, 3 national clinical trials steering committees, and statistical liaison responsibilities with 3 national cancer clinical trials organizations. He is on the editorial boards of CCR and JNCI.

1. Planning the duration of a comparative clinical trial. J Chron Dis, 1981.
2. Display and analysis of patterns of differential activity of drugs. JNCI, 1989.
3. Comparison of in vitro anticancer drug screening data generated with a tetrazolium assay versus a protein assay. JNCI, 1990.
4. Discrimination techniques applied to the NCI in vitro antitumor drug screen, Stat in Med, 1994.
5. Accelerated titration designs for phase 1 clinical trials, JNCI, 1997.
6. New guidelines to evaluate the response to treatment in solid tumors, JNCI, 2000.
7. Correlations between the NCI pre-clinical models and drug activity in human clinical trials, Br J of Cancer, 2001.
8. Risks and benefits of phase 1 oncology research 1991-2002, NEJM, 2005.
9. Randomized phase 2 design issues, JCO, 2005.
10. Compressing drug development timelines in oncology using phase '0' trials, Nat Rev Cancer, 2007.
11. Validation of novel imaging methodologies, EJOC, 2009.

Manfred SCHMITT, PhD, MD sci

Born on September 7, 1947, Nordenham, Germany, married to Elisabeth Schmitt, one daughter, Michaela, born 1979. 1969–1978: Studies in chemistry, biology and biochemistry. 1974–1978: Diploma (masters) in biology. Certificate to teach chemistry and biology for Senior High School (Gymnasium). Ph.D. in biochemistry (Dept. Biochemistry, University of Mainz, Germany). 1978–1981: Assistant-Prof. (Dept. Med. Microbiology, University of Mainz, Germany). 1981–1983: Visiting Investigator (Scripps Clinic and Research Foundation, Dept. Immunopathology, La Jolla, California, USA). 1983–1987: Associate-Prof. (Dept. Pathology, University of Berne, Switzerland). 1987–1993: Associate Prof. and Director of Clinical Research Unit, Dept. Ob&Gyn (Frauenklinik), Klinikum rechts der Isar, Technical University of Munich, Germany. 1989: Habilitation and Privatdozent (Dr. med. habil., Dr. med. sci.) in Experimental Gynecology, Technical University of Munich. 1993–today: Full Professor (C3) of Experimental Gynecology and Director of Clinical Research Unit, Dept. Ob&Gyn, Technical University of Munich, Germany.

360 full publications in scientific journals and books, more than 400 presentations at meetings and institutional seminars. 72 patents/patent applications. In charge of 110 dissertations and 13 habilitations. Organizer of 35 national/international conferences. Co-editor of Thrombosis and Haemostasis, European Journal of Cancer, International Journal of Oncology, Cancer Therapy, Critical Reviews in Clinical Laboratory Science, The Open Clinical Chemistry Journal, Thrombosis Research (terminated).

Co-founder of Wilex Biotechnology GmbH (now Wilex AG), Munich, Germany, in 1997. Member of several (inter)national scientific societies. National and international research funding.

Present research focus: Breast cancer, ovarian cancer, lung cancer, melanoma, metastasis research, cancer biomarkers, cell signalling, DNA-methylation, tumor-associated proteolysis, genomics, proteomics, biosensors.

Lalitha K. SHANKAR, MD, PhD

Lalitha K. Shankar, MD, PhD, is at the Cancer Imaging Program at the National Cancer Institute, at the National Institutes of Health in Bethesda, MD. Since joining NCI in 2003, she has served as an Advisor to the Associate Director of the Division of Cancer Treatment and Diagnosis. Her research interests have been both in the role of functional and molecular imaging in the diagnosis and treatment of cancer, as well as evaluating the performance characteristics of imaging modalities for optimal use in the management of the cancer patient. Her work involves establishment of and monitoring of clinical trials to evaluate imaging tracers and techniques, which aim to improve the prevention, diagnosis and treatment of cancer. She provides imaging expertise for ongoing trials of cancer therapeutics sponsored by NCI. She manages the imaging cooperative group ACRIN and the Phase I and II Imaging Trials Contract Program and is the Acting Chief of the Clinical Trials Branch at the Cancer Imaging Program.

Eric J. SMALL, MD

Dr. Small is Professor-in-Residence of Medicine and Urology, and Leader of the Prostate Cancer Program in the Helen Diller Family Comprehensive Cancer Center. He has contributed a significant body of work to the understanding of advanced prostate cancer, with themes involving the transition from hormone-sensitive to castration-resistant prostate cancer, the development of androgen receptor directed therapies, the development of risk assessment tools for patients with advanced prostate cancer, and prostate cancer immunotherapy.

Dr. Small is PI for UCSF as one of eight Prostate Cancer Foundation therapy consortium members. He serves as institutional Principal Investigator for UCSF's participation in the Department of Defense Prostate Cancer Clinical Consortium.

Dr. Small has served on the NCI Prostate Cancer Progress Review Group, and was recently appointed Associate Editor of the Journal of Clinical Oncology, where he is responsible for Genitourinary Oncology. He served as the Scientific Program Committee Chair in the American Society of Clinical Oncology (ASCO) in 2004. Additionally, he was a co-founder, and subsequently Chaired the First Annual Multidisciplinary Clinical Prostate Cancer Symposium, jointly co-sponsored by ASCO, ASTRO, the SUO and the PCF, which has since evolved into the Multidisciplinary Genitourinary Oncology Symposium. Dr. Small has served as Chair of the Genitourinary Committee of the Cancer and Leukemia Group B (CALGB) since, an NCI Cooperative Group. Dr Small was recently appointed to the Board of Directors of the American Board of Internal Medicine, serving on the Subspecialty Board on Medical Oncology.

Recently Dr. Small was appointed Chief of the Division of Hematology and Oncology as well as Deputy Director and Director of Clinical Sciences in the UCSF Helen Diller Family Comprehensive Cancer Center.

Vered STEARNS, MD

Associate Professor of Oncology, Breast Cancer Program, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins School of Medicine

Dr. Stearns completed a B.S. equivalent at the Sackler Faculty of Medicine, Tel-Aviv University, in Israel in 1989. Dr. Stearns completed her medical school training at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, where she received her M.D. in 1992. She completed her Internal Medicine residency at Georgetown University Medical Center in Washington, DC in 1995. She subsequently completed a Medical Oncology Fellowship at Georgetown University and the Lombardi Cancer Center when she developed interest in translational breast cancer research. Dr. Stearns was a faculty member at the Lombardi Cancer Center at the Georgetown University from 1999 to 2001 and at the University of Michigan Comprehensive Cancer Center in Ann Arbor, Michigan from 2001 to 2002. Dr. Stearns has joined the faculty at the Breast Cancer Program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in 2002.

Dr. Stearns's long-term research goal is to improve upon current practices by individualizing strategies for the treatment and prevention of breast cancer. While administering standard chemotherapy in the preoperative setting, Dr. Stearns examines molecular markers and functional imaging that may assist in early determination of sensitivity or resistance to specific treatments while administering new agents that target epigenetic changes. The long-term goal is to add novel agents to standard regimens using surrogate markers as endpoints. Her work has been supported by the prestigious Damon Runyon Clinical Investigator Award, the American Society of Clinical Oncology Advanced Clinical Investigator Award, and by grants from the NIH, NCI, and from several foundations. Dr. Stearns is a member of the Pharmacogenetics Netwrok's Consortium On BReast cAncer (COBRA) Group, funded by the NIH/NIGMS to evaluate the role of genetic polymorphism in efficacy and safety to common breast cancer treatments such as tamoxifen and aromatase inhibitors. Dr. Stearns has also spent considerable effort focusing on improving the quality of life of women who have survived their breast cancer and suffer bothersome symptoms related to cancer therapies.

Roger STUPP, MD

Roger Stupp, M.D. is head of the Department of Oncology of the Riveria/Chablais region at the hospitals of Vevey and Monthey, Switzerland, and he serves as Attending Physician at the Department of Neurosurgery of University of Lausanne Medical Center (CHUV) where he leads the multidisciplinary brain tumor clinic.

Dr. Stupp is an active and dedicated clinical researcher. His special clinical interests include the multimodality management of primary and secondary brain tumors, head and neck and lung cancers, new drug development and the association of chemotherapy and radiation therapy. He is also closely involved in bringing new antiangiogenic and biological treatments to the clinic. Dr. Stupp maintains close collaborations with the Laboratory of Tumor Biology and Genetics at the CHUV, Laboratory of Tumor Angiogenesis and Melanoma Research, and the Swiss Institute of Experimental Cancer Research (ISREC).

Roger Stupp has been the lead investigator for establishing temozolomide chemotherapy in conjunction with radiotherapy in newly diagnosed glioblastoma, and determining the predictive value of MGMT gene promoter methylation. Recent work includes the association of the integrin inhibitor cilengitide in addition to chemoradiotherapy, currently under investigation in a randomized phase III trial. He co-chairs a randomized clinical trial by the Swiss Group for Clinical Cancer Research (SAKK) investigating chemotherapy and concomitant radiotherapy in lung cancer brain metastases.

As Vicepresident of the European Organization for Research and Treatment of Cancer (EORTC) he serves as a Member of the EORTC Executive Committee and Board. From 2003–2009 he served as the Secretary of the Brain Tumor Group. In addition, Dr. Stupp is a member of the editorial boards of numerous journals including Journal of Clinical Oncology, Lancet Oncology and Neuro-Oncology.

Dr. Stupp received his medical degree from Zurich University Medical School, Zurich, Switzerland. He completed training in Internal Medicine at the Langenthal/Bern County Hospital and the University Hospital of Zurich, Switzerland. Dr. Stupp pursued and completed specialization in hematology and oncology, spending three years as a fellow in medicine, hematology/oncology at the University of Chicago Hospitals and Cancer Center, Chicago, Ill., USA.

Fred C.G.J. SWEEP, PhD

Fred C.G.J. Sweep (1959) is full professor of Chemical Endocrinology and head of the department of Laboratory Medicine (400 fte) at the Radboud University Nijmegen Medical Centre (RUNMC). He is board certified in Clinical Chemistry and Endocrinology by the Netherlands Society for Clinical Chemistry and Laboratory Medicine, and registered as a European Clinical Chemist. He studied Medical Biology at the University of Utrecht (1979–1985), where he also obtained his PhD degree (1989) in Pharmacology. He had his training as a clinical chemist at the RUNMC (1991–1995), where he also completed his training in Endocrinology (1998).

Fred Sweep is a reviewer of many journals, member of Editorial boards and has published over 280 papers in peer-reviewed journals (PubMed search code: fred sweep or sweep c or sweep f). Fred Sweep is an active member of many different national and international societies devoted to cancer biomarkers. He is immediate past secretary of the PathoBiology Group of the European Organisation for Research and Treatment of Cancer (EORTC) and chairman of the Quality Assurance committee within this group. He also was chairman of the Translation Research Advisory Committee of the EORTC and EORTC Executive Committee member (2006–2009). In 2006 he chaired the 4th International NCI–EORTC Meeting on Molecular Markers in Cancer, in Atlanta, US. Fred Sweep's department has developed international Quality Assurance programs for steroid hormone receptors and other biomarkers since 1975. In the early 1990s more than 160 laboratories worldwide participated in these programs. Presently, QA programs are running for large multicentre prospective clinical trials on biomarkers in Europe. His current research interests are focused on development of new antibody based assays for biomarkers in oncology with emphasis on proteases and angiogenesis. Within the field of Endocrinology Sweep's department has a long-standing expertise in thyroid and steroid hormones within special interest in the hypothalamus-pituitary adrenal/gonadal axis and free hormones. The department of Laboratory Medicine harbours all up-to-date laboratory facilities for Clinical Chemistry, Endocrinology, Haematology, Immunology, Paediatrics and Neurology.

Sabine TEJPAR, MD, PhD

After a training in Internal medicine and Gastro Enterology and a Ph.D in the program of Molecular Oncology at the Center for Human Genetics, KULeuven, I became in 09–2003 an Associate Professor in the Dept of Gastro Enterology, Digestive Oncology Unit, UZ Leuven. I work as a part time clinician, part time researcher (Senior Clinical Investigator of the Fund for Scientific Research – Flanders [Belgium]), with a focus on basic and translational research in colorectal cancer.

My main research projects involve prognostic markers in adjuvant colorectal cancer and predictive markers for efficacy of EGFR inhibition.

Gerry THOMAS, BSc, PhD

Professor Gerry Thomas is a serial biobanker. She graduated from Bath University in 1982 with a degree in Pharmacology and completed a PhD in Pathology at the University of Wales College of Medicine, Cardiff in 1988. In 1992 she left Cardiff to work at the Department of Pathology at the University of Cambridge, and in 2002, she returned to Wales as a Senior Lecturer, then Professor (in 2006) in Molecular Oncology at Swansea University, just as a grant was awarded from the Welsh Assembly Government to Professor Malcolm Mason and others in Cardiff to establish the Wales Cancer Bank, a national collection of blood samples and tissue from cancer patients operated in Wales. She took responsibility as Principal Scientist for the bank in steering the project through Ethics approval, and developing the scientific protocols required to run the project. In 2007, she took up a position as Professor of Molecular Pathology at Imperial College London, where she is involved in the management of the Hammersmith Biomedical Resource Centre. She still continues to work part-time for the Wales Cancer Bank as Scientific Director. She has coordinated the Chernobyl Tissue Bank (CTB) since its inception in 1998. The CTB is a unique resource of biological samples from young onset thyroid cancer and underpins a number of international projects on the pathobiology of radiation related thyroid cancer. She combines her tissue banking activities with research on the molecular pathology of thyroid and breast cancer, and is also actively involved in translational studies related to clinical trials in breast cancer both in the UK and internationally. She is a member of the EORTC Pathobiology Group and has published extensively on the clonal origin of tissues, the molecular pathology of thyroid cancer and more recently on the molecular biology of breast cancer.

Christoph THOMSSEN, Prof Dr med

Education and degrees: Medical School at the Georg-August-University Goettingen and the Technische Universitaet Munich. 1991: Specialist's degree in Obstetrics and Gynaecology (German National Board Examination). 1998: Lecturer ("Privatdozent") at the Faculty of Medicine of the University Hamburg. 2001: University-Professor for Obstetrics and Gynaecology at the University Hamburg (Associate Professor). 2004: University-Professor for Obstetrics and Gynaecology at the Martin-Luther-University Halle-Wittenberg (Full Professor).

Professional appointments: From 1984 residency and fellowship at the Departments of Obstetrics and Gynaecology District Hospital Fuerstenfeldbruck (Head: Dr. med. S. Keck) and Technische Universitaet Munich (Head: Prof. Dr. med. H. Graeff). 1992: Senior physician at the Department of Obstetrics and Gynaecology of the Technische University Munich. 1996: Associate director at the Department of Obstetrics and Gynaecology, University of Hamburg (Head: Prof. Dr. med. F. Jaenicke). 2003: Head of the Department of Gynaecology at the Martin-Luther-University, Halle (Saale).

Subjects of Research: Breast cancer: surgical and medical treatment of primary disease and recurrence; prognostic and predictive factors; endocrine therapy, targedted drugs, chemotherapy incl. dose-intense chemotherapy; axillary dissection, quality of life. Ovarian Cancer: Debulking surgery. Cervical Cancer: Neoadjuvant chemotherapy, minimal invasive surgery. Clinical Studies: Participation in study design and coordination of sveral clinical studies (e.g. Chemo-N0, NNBC–3 Europe); active participation in more than 50 clinical trials.

Memberships: American Association of Cancer Research (AACR), Deutsche Krebsgesellschaft (DKG), Deutsche Gesellschaft für Gynaekologie und Geburtshilfe (DGGG), Deutsche Gesellschaft für Senologie (DGS), Arbeitsgruppe Gynaekologische Onkologie (AGO), AGO Breast Study Group (AGO-B), Deutsche Krebshilfe (German Cancer Aid, Fachausschuß Klinische Studien), EORTC PathoBiology Group (PBG), EORTC Breast Cancer Group (BCG), Nordostdeutsche Gesellschaft für Gynaekologische Onkologie (NOGGO), Mitteldeutsche Gesellschaft für Frauenheilkunde und Geburtshilfe e.V. (MGFG).

Publications: >80 original papers and review papers, >40 book articles und published lectures, > 250 abstracts and letters, > 500 lectures and oral presentations.

Editor: "Breast Care" (Karger). Scientific Board Member: Senologie (Thieme).