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| **BIOGRAPHICAL SKETCH**Provide the following information for the Senior/key personnel and other significant contributors.Follow this format for each person.  **DO NOT EXCEED FOUR PAGES.** |
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| NAMEMiele, Lucio | POSITION TITLEProfessor of Medicine, Director for Inter-Institutional Programs, Stanley Scott Cancer Center, LSU Health Sciences Campus |
| eRA COMMONS USER NAME (credential, e.g., agency login)lmiele |
| EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)* |
| INSTITUTION AND LOCATION | DEGREE*(if applicable)* | MM/YY | FIELD OF STUDY |
| University of Naples, Italy | MD | 03/82 | Medicine |
| University of Naples, Italy | PhD | 01/88 | Biochemistry |
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1. **Personal Statement**

Molecular genetics has been at the core of Dr. Miele’s research since his PhD dissertation work on microbial DNA sequencing at the Max-Planck Institute for Molecular Genetics in Berlin. During his postdoctoral fellowship training at the NIH’s Section on Developmental Genetics, Human Genetics Branch (NICHD), he developed novel expression vectors, invented an early version of PCR-ELISA using product capture by biotinylated primers and identification by digoxygenin-conjugated probes. He was an early adopter of bio-informatics to identify the active sites of immunomodulatory proteins. At Loyola University Medical Center, Dr. Miele created, equipped and oversaw a Molecular Pathology Core featuring RNA and DNA isolation from clinical specimens, real-time Q-RT-PCR and sequencing. Currently, a large part of Dr. Miele’s work is devoted to biomarker discovery for mechanism-based therapeutic trials and mechanistic investigations of cancer stem cell-regulatory genes such as Notch. Another emphasis of Dr. Miele’s work is correlation between GWAS data and transcriptome for genes associated with breast and prostate cancer risk in collaboration with Dr. Hicks. Dr. Miele has served as co-chair of the CTEP IDSC task force on drugs targeting cancer stem cell pathways. His translational research focuses on the effects of Notch inhibition on cancer cells and cancer stem cells. Between 2009 and 2014, Dr. Miele developed 6 Cancer Institute Cores (Molecular Genomics, Cancer Bio-Informatics, Tissue Microarrays/Biobanking, Animal Imaging, Cancer Drug Discovery and Flow Cytometry). Dr. Miele’s has a long-standing commitment to the mentoring of junior faculties. At Loyola University, where he served as Breast Cancer Program Director and Associate Cancer Center Director for Translational Science, he mentored 5 junior Faculties, all of whom have achieved NIH funding, and three are now tenured Associate or Full Professors. At the UMMC Cancer Institute, Dr. Miele oversaw more than 30 research groups organized into 3 basic and one clinical program devoted to cancer research. During this time, Dr. Miele developed 6 Cancer Institute Cores (Molecular Genomics, Cancer Bio-Informatics, Tissue Microarrays/Biobanking, Animal Imaging, Cancer Drug Discovery and Flow Cytometry). He recruited 9 senior and 2 junior investigators (A. Levenson and K. Xu). Both have obtained national funding within 3 years. In addition, Dr. Miele is a mentor for the JSU RCMI on environmental toxicology/carcinogenesis (P. Tchounwou, PI, C. Yedjou, mentee, 2G12RR013459-11). He serves on the External Advisory Board of Tulane’s Cancer Genetics COBRE (P. Deininger, PI, P20 RR020152).

**Positions and Employment**

1984-1986 Graduate student, Max-Planck Institut fuer Molekulare Genetik, Berlin FRG, where he

 conducted Ph.D. dissertation work on plasmid RP4 DNA primase genes and contiguous genes,

 including the kanamycin-resistance gene. Co-advisor was Dr. Erich Lanka (Abteilung

 Schuster). (30) 8307-242.

1982-1983 Instructor, Institute of Biological Chemistry, First Faculty of Medicine and Surgery, University

 of Naples. Taught Biochemistry lab for medical students in University of Naples. Gave lectures

 for official courses of Biochemistry for medical students and was a member of the board of

 examiners.

1982-1983 Instructor, Institute of Biological Chemistry, First Faculty of Medicine and Surgery, University of

 Naples

1986-1988 Visiting Fellow, Human Genetics Branch, Section on Developmental Genetics, NICHD, NIH

1989-1990 Adjunct Scientist, Section on Developmental Genetics, Human Genetics Branch, NICHD, NIH

1990-1994 Visiting Associate, Section on Developmental Genetics, Human Genetics Branch, NICHD,

1994-1998 Member, Division of Clinical Trials Design and Analysis, CBER/FDA NIH

1994-1997 Tenure-track Principal Investigator, Laboratory of Cell Biology, Division of Monoclonal

Antibodies, CBER, FDA

1997-1998 Acting Chief, Laboratory of Cell Biology, Division of Monoclonal Antibodies, CBER, FDA; Chairperson, CBER scientists

1998-2001 Assistant Professor, Department of Pathology, Cardinal Bernardin Cancer Center, Loyola

University Chicago Medical Center, Maywood, IL; Chair, Admission committee to the Graduate Program in Molecular Biology; Director, DNA Sequencing and Recombinant DNA Laboratory, and Proteomics Laboratory, Molecular Pathology Research Facility, Department of Pathology

2001-2005 Associate Professor of Pharmacology with tenure, University of Illinois at Chicago; Director, Molecular Pathogenesis and Signaling Program, UIC Cancer Center

2005 Professor with tenure of Pathology and Pharmacology, Director, Breast Cancer Research Program, Cardinal Bernardin Cancer Center, Loyola University Chicago

2007-2009 Associate Director for Translational Science, Cardinal Bernardin Cancer Center, Loyola

University Chicago

2009-2014 Director, University of Mississippi Medical Center Cancer, Ergon Professor of Medicine and Pharmacology

2014-present Professor of Medicine, LSU Health Sciences Center, Director of Inter-institutional Programs, Stanley S. Scott Cancer Center

**Other Experience and Professional Memberships**

**Administrative and Scientific Institutional Leadership Positions:**

2003-2005 Director, Molecular Pathogenesis and Signaling Program, UIC Cancer Center

2005-2009 Director, Breast Cancer Research Program, Cardinal Bernardin Cancer Center

2008-2009 Associate Director for Translational Sciences, Cardinal Bernardin Cancer

2009-2014 Director, University of Mississippi Medical Center Cancer Institute. Supervises and organizes

 basic, translational and clinical cancer research, cancer clinical care and cancer outreach and

education at the University of Mississippi Medical Center

2014- Director of Inter-Institutional Programs, Stanley S. Scott Cancer Center, LSU. Coordinates collaborative translational and clinical research programs with other members of the Louisiana Cancer Research Consortium and with other regional academic institutions

2010-present Member, Mid-South Board of Directors, American Cancer Society

**Member:** AACR, ASCO, ACS

**Selected Journals and Granting Agencies for which Dr. Miele has served as a referee:**

Nature Cell Biology, Nature Communications, Cancer Cell, P.N.A.S., Oncogene, Cancer Res., J. Clin Invest., In. J. Cancer, Biochemical J., Gastroenterology, Biochemistry, J. Immunol., European Journal of Biochemistry, European Journal of Cell Biology, Exp. Cell Res., Blood, PLoS Medicine, J. Leukocyte Biol., Gene, Leukemia, Cell Death and Differentiation, J. Cell Physiol., Mol. Cancer Ther., Cell and Tissue Res., Future Med., Mol. Medicine Book Series (Humana Press), Arch. Pathol. Lab Med., DNA and Cell Biol., Curr. Molecular Med., Clin. Cancer Res., Br. J. Cancer, J. Biol. Chem., Int. J. Cancer, Stem Cells and Development, Biotechnology, The Histochemical Journal, Clin. Diagn. Lab Immunol., Amino Acids, Prostaglandins. The Wellcome Trust Fund, NIH (ET-1, DMP, CTSA, BMCT, NCI PO1, CB), NCRR/NCATS (CTSA), DOD, VA, ALW (The Netherlands), NSERC (Canada), AIRC (Italy), Cancer Research UK.

**Editorial Boards**:

J. Cancer Treatment and Metastasis (Editor in Chief), Frontiers in Molecular Medicine, Frontiers in Oncology (Associate Editor); J. Cell. Biochem. (Associate Editor), J. Exp. Clin. Canc. Res. (Executive Editor for the Americas), Curr. Mol. Med. (Associate Editor), Am. J. Cancer Res.; Women’s Oncology Reviews (Assistant Editor)

**Public Health Responsibilities at FDA:**

1995-1997 Chairperson, Re-writing of the current Points to Consider in the Manufacture and Testing of

 Monoclonal Antibody Products for Human Use, issued in the U.S. Fed. Register 62 FR vol 40,

 2/28/97, http://www.fda.gov/cber/points.htm

1994-1998 Member of policy groups drafting other guideline documents pertaining to biotechnology drugs,

 including ICH (International Conference on Harmonization) guidelines.

1994-1998 Had review and supervisory responsibilities in the review of novel monoclonal antibodies to

 tumor antigens and viral antigens for diagnostic and therapeutic use.

* 1. Had clinical review responsibilities for trials of biotechnology products, predominantly in the

 area of immunomodulatory agents.

**Honors**

1982 First in his M.D. class with highest GPA in the history of his Medical School

1983 Award for Outstanding Young Scientist, the Academy of Medical and Surgical Sciences,

 National Society of Sciences, Literature and Arts, Naples, Italy

1997 FDA Honor Award “for exceptional performance”, 1997

1998 FDA/OTRR “On the spot” award for outstanding performance as an Acting Lab Chief and

 for contributions to FDA policy

2000 Honored by Illinois Lieutenant Governor for contributions to women’s cancer research

2001 Honored by Illinois Lieutenant Governor for contributions to women’s cancer research

2005 Organizer and invited featured speaker, EMBO Workshop on Notch signaling in

 Development and Cancer, Rome, Italy

2006 Keynote Speaker, Italian Society of Neuroendocrinology, Florence and Milan, Italy

2007 Organizer, Invited Speaker: the Notch Conference, Athens, Greece

2007 Chair, Translational Symposium: The Notch Conference, Athens, Greece

2007-present Adjunct Professor, Department of Biopharmaceutical Sciences, University of Illinois at Chicago

2007-present Adjunct Professor, Department of Biology, Temple University, Philadelphia

2008-present Member and co-Chair, NCI Task Force on Cancer Stem Cells

2008 Invited Speaker, the NCI Translates Conference (invitational only)

2008 Invited to be Editor of a new medical textbook on “Cancer Therapeutics”, World Scientific

 Press International, Singapore, London, New York.

2009 Organizer, the Notch conference, Athens, Greece, October 2009

2009 Symposium Chair, Early Clinical Trials Pipeline, International Conference on Drug

 Discovery Science and Technology, Shanghai, China

2011 Organizer, 1st International Conference, Mykonos, Greece

2012 International Research Award: Schola Medica Salernitana (Italy)

2012 Acharya P.C. Ray Gold Medal Award for Pioneering Research (India Science News Association)

1. **Selected Peer-reviewed Publications (Selected from >190 peer-reviewed publications)**
2. Zhang S, Chung WC, Miele L, Xu K. Targeting Met and Notch in the Lfng-deficient, Met-amplified triple-negative breast cancer. Cancer Biol Ther. 2014 Feb 20;15(5). PMID: 24556651.
3. Zhu H, Bhaijee F, Ishaq N, Pepper DJ, Backus K, Brown AS, Zhou X, Miele L. Correlation of Notch1, pAKT and nuclear NF-kappaB expression in triple negative breast cancer. Am. J Cancer Res. 3:230-239 (2013) PMID: 23593544
4. Yun J, Pannuti A, Espinoza I, Zhu H, Hicks C, Zhu X, Caskey M, Rizzo P, D'Souza G, Backus K, Denning MF, Coon J, Sun M, Bresnick EH, Osipo C, Wu J, Strack PR, Tonetti DA, Miele L. Crosstalk between PKCα and Notch-4 in endocrine-resistant breast cancer cells. Oncogenesis 2013 Aug 5;2:e60. doi: 10.1038/oncsis.2013.26. (2013) PMID: 23917222
5. Hicks C, Kumar R, Pannuti A, Backus K, Brown A, Monico J, Miele L. An Integrative Genomics Approach for Associating GWAS Information with Triple-Negative Breast Cancer. Cancer Inform. 12:1-20 doi: 10.4137/CIN.S10413. Epub;%2013 Jan 29. (2013) PMID: 23423317
6. Hicks C, Koganti T, Brown A, Monico J, Backus K, Miele L. Novel integrative genomics approach for associating GWAS information with intrinsic subtypes of breast cancer. Cancer Inform. 12: 125–142 doi: 10.4137/CIN.S11452 (2013) PMID: 23761956
7. Hicks C, Miele L, Koganti T, Young-Gaylor L, Rogers D, Vijayakumar V, Megason G. Analysis of Patterns of Gene Expression Variation within and between Ethnic Populations in Pediatric B-ALL. Cancer Inform. 2013 Aug 27;12:155-73. doi:10.4137/CIN.S11831. PubMed PMID: 24023509; PubMed Central PMCID: PMC3762614
8. Mo YY, Tang H, Miele L. Notch-associated microRNAs in cancer. Curr. Drug Targets 2013 Sep;14(10):1157-66. PMID: 23834150
9. Hicks C, Kumar R, Pannuti A, Miele L. Integrative Analysis of Response to Tamoxifen Treatment in ER-Positive Breast Cancer Using GWAS Information and Transcription Profiling. Breast Cancer (Auckl.) 6:47-66 (2012) doi: 10.4137/BCBCR.S8652. Epub;%2012 Feb;%20.47-66
10. Gu JW, Young E, Patterson SG, Makey KL, Wells J, Huang M, Tucker KB, Miele L. Postmenopausal obesity promotes tumor angiogenesis and breast cancer progression in mice. Cancer Biol Ther. 2011 May 15;11(10):910-7. Epub 2011 May 15. PMID: 21451264; PubMed Central PMCID: PMC3230297.
11. Hicks C., Asfour R., Pannuti A., Miele L. An integrative genomics approach to biomarker discovery in breast cancer. Cancer Inform. 10:185-204 (2011) PMID: 22399860
12. Pallavi SK, Ho DM, Hicks C, Miele L, Artavanis-Tsakonas S. Notch and Mef2 synergize to promote proliferation and metastasis through JNK signal activation in Drosophila. EMBO J. 2012 May 11;31(13):2895-907. doi: 10.1038/emboj.2012.129. PMID: 22580825
13. Miele L. Transcription factor RBPJ/CSL: A genome-wide look at transcriptional regulation. Proc Natl Acad Sci U S A. 108(36):14715-6 (2011) PMID: 21873209
14. **Research Support**

**Ongoing Research Support**

1. NCI 1P01CA166009-01A1 Targeting Multiple Diseases through Gamma Secretase L. Miele, Co-PI (B. Osborne, U. Mass.)

 5 years, $1,114,000 (for L.M. project)

 2013-2018 (1.8 CM) L. Miele, Project 1 PI

2. Validation of a Novel Notch-Driven Cancer Stem Cell Gene Signature for Anti-Notch Therapy in Estrogen Receptor Positive Breast Cancer

 Breast Cancer Research Foundation (Albain)

 $239,027 (Oct 1 2013-Oct 1, 2014, 0.24 CM) L. Miele, Co-investigator

2. NCI U54CA153719 Deep South Network Cancer Control (Partridge)

 2010-2015 $51,501 (0.5 CM) L. Miele, Co-PI

3. NIGMS P20GM103501 Mentoring Translational Researchers in Louisiana (Ochoa)

07/01/2010-06/30/2015 $1,506,696 (0.6 CM) L. Miele, Mentor

4. R13MD008590 Molecular Bases of Health Disparities (Estrada)

07/09/2013 – 06/30/2014 $43,889 No Add. Eff. L. Miele, Scientific Advisory Committee.

5. RCMI (Jackson State University, P. Tchounwou, PI). Role: L. Miele, Mentor. No Add Eff.

Major goals: the JSU RCMI focuses on environmental carcinogenesis and cancer drug development. Dr.

**Pending Grants and Contracts**

1. 1. NCI PAR-12-094 Molecular Basis of Health of Health Disparities in Triple-Negative Breast Cancer (Hicks)

11/01/2014-10/31/2016 $175,000/annual direct (0.6 CM) L. Miele, Consortium PI

2. NIGMS   PAR14-178 Mentoring Translational Researchers in Louisiana (Ochoa) 07/01/2015-06/30/2020 $750,000 annual direct (1.8 CM) L. Miele, Pilot Project Program Co-Director

3. NIGMS P20GM109093-01A1 Center for Translational Viral Oncology (Reiss)        9/01/2014-08/31/2019 $1,221,367 (0.6 CM) L. Miele, Scientific Advisor

4. CCTS (CTSA) Consortium with UAB (Kimberly)

 2014-2018 (1.2 CM effort) L. Miele, Co-PI

**Completed Recent Research Support**

1. 1R01 CA122914-01 Tonetti (PI) 05/01/07 – 04/30/12 0.93 calendar

National Cancer Institute, NIH 58,000

PKC Alpha as a marker for Logical Therapeutic Approaches to Breast Cancer L. Miele, co-PI

1. 1P01 AG025531 (Osborne) 07/01/06 – 6/30/11 2.18 calendar

National Institute on Aging, NIH $1,114,000

University of Massachusetts Anti-neoplastic effects of gamma secretase inhibitors

Miele, L (Co-PI)

1. KG080310 (Foreman) 07/19/08 – 06/30/11 .6 calendar

Komen for the Cure Investigator Initiated Research Grant $600,000

Notch signaling and hepatocyte growth factor in breast cancer

Foreman, K (PI) Miele, L (Co-PI)