BIOGRAPHICAL SKETCH

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NAME: Winer, Eric P.

eRA COMMONS USER NAME (credential, e.g., agency login): ewiner01

POSITION TITLE: Professor of Medicine, Harvard Medical School

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Yale University, New Haven, CT	BA	06/1978	History & Russian Studies
Yale University School of Medicine, New Haven, CT	MD	06/1983	Medicine

A. Personal Statement.

I am a Professor of Medicine at Harvard Medical School and Chief of Women's Cancers at Dana-Farber Cancer Institute. I am also Director of the Breast Oncology Program and the Thompson Chair in Breast Cancer Research. I divide my time between clinical work, clinical research, and administration. Since I joined the Harvard faculty in 1997, I have mentored over 20 fellows and junior faculty, the vast majority of whom have gone on to assume positions in major cancer academic cancer centers. I have been the co-chair of the Breast Committee for the Cancer and Leukemia Group B and now the Alliance, but am stepping down from that role in May, 2016. I am also the leader of the Dana-Farber/Harvard SPORE (Specialized Program in Research Excellence) in breast cancer. Finally, I have served as the Chief Scientific Advisor to Susan G. Komen for the Cure since 2007. Broadly defined, the focus of my research has been on improving the clinical care of women with breast cancer. I have approached this task with a collaborative spirit, and have worked closely with colleagues in basic science, translational medicine, biostatistics, health services research, clinical oncology, and psychosocial research. I have conducted a wide array of Phase I, II, and III clinical trials in patients with breast cancer. These trials have addressed all of the major biologic subtypes and all stages of the disease.

1. Burstein HJ, Kuter I, Campos SM, Gelman RS, Tribou L, Parker LM, Manola J, Younger J, Matulonis U, Bunnell CA, Partridge AH, Richardson PG, Clarke K, Shulman LN, Winer EP. Clinical Activity of Trastuzumab and Vinorelbine in Women with HER2 Overexpressing Metastatic Breast Cancer. J Clin Oncol. 2001;19(10):2722-30. PMCID not needed
2. Burstein HJ, Harris LN, Gelman R, Lester SC, Nunes RA, Kaelin CM, Parker LM, Ellisen LW, Kuter I, Gadd MA, Christian RL, Kennedy PR, Borges VF, Bunnell CA, Younger J, Smith BL, Winer EP. Preoperative Therapy with Trastuzumab and Paclitaxel Followed by Sequential Adjuvant Doxorubicin/Cyclophosphamide for HER2 Overexpressing Stage II or III Breast Cancer. J Clin Oncol. 2003;21(1):46-53. PMCID not needed
3. Ligibel JA, Campbell N, Partridge A, Chen WY, Salinardi T, Chen H, Adloff K, Keshaviah A, Winer EP. Impact of a mixed strength and endurance exercise intervention on insulin levels in breast cancer survivors. J Clin Oncol. 2008 Feb 20;26(6):907-12. PMCID not needed
4. Partridge A, Adloff K, Blood E, Dees EC, Kaelin C, Golshan M, Ligibel J, de Moor JS, Weeks J, Emmons K, Winer E. Risk perceptions and psychosocial outcomes of women with ductal carcinoma in situ: longitudinal results from a cohort study. J Natl Cancer Inst. 2008 Feb 20;100(4):243-51.Epub 2008 Feb 12.PMCID not needed.
5. Goel S, Wang Q, Watt AC, Tolaney SM, Dillon DA, Li W, Ramm S, Palmer AC, Yuzugullu H, Varadan V, Tuck D, Harris LN, Wong KK, Liu XS, Sicinski P, Winer EP, Krop IE, Zhao JJ. Overcoming

Therapeutic Resistance in HER2-Positive Breast Cancers with CDK4/6 Inhibitors. Cancer Cell. 2016 Mar 14;29(3):255-69. doi: 10.1016/j.ccell.2016.02.006.; PMCID: PMC4794996.

6. Freedman RA, Gelman RS, Wefel JS, Melisko ME, Hess KR, Connolly RM, Van Poznak CH, Niravath PA, Puhalla SL, Ibrahim N, Blackwell KL, Moy B, Herold C, Liu MC, Lowe A, Agar NY, Ryabin N, Farooq S, Lawler E, Rimawi MF, Krop IE, Wolff AC, Winer EP, Lin NU. Translational Breast Cancer Research Consortium (TBCRC) 022: A Phase II Trial of Neratinib for Patients with Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer and Brain Metastases. J Clin Oncol. 2016 Mar 20;34(9):945-52. Epub 2016 Feb 1. PMCID not available.

B. Positions and Honors.

Positions and Employment:

1986-87 **Intern, Resident, Chief Resident**, Internal Medicine, Yale-New Haven Hospital, New Haven, CT
1987-89 **Fellow**, Hematology/Oncology, Duke University Medical Center, Durham, NC
1989-90 **Associate in Medicine**, Duke University Medical Center, Durham, NC
1991-96 **Assistant Professor of Medicine**, Duke University Medical Center, Durham, NC
1993-97 **Co-Director**, Multidisciplinary Breast Program, Duke University Medical Center, Durham, NC
1996-97 **Associate Professor of Medicine**, Duke University Medical Center, Durham, NC
1997-2008 **Associate Professor of Medicine**, Harvard Medical School, Boston, MA
1997- **Director**, Breast Oncology Center, Dana-Farber Cancer Institute, Boston, MA
2003-2016 **Co-Chair**, Alliance for Clinical Trials Breast Committee
2007- **Chief Scientific Advisor and Co-Chair**, Scientific Advisory Board, Susan G. Komen for the Cure
2008- **Chief**, Division of Women's Cancers, Dana-Farber Cancer Institute, Boston, MA
2008- **Professor of Medicine**, Harvard Medical School, Boston, MA
2010- **Director**, Breast Program, Dana-Farber/Harvard Cancer Center, Boston, MA
2013-2015 **Chai**r, Executive Committee for Clinical Programs, Dana-Farber Cancer Institute
2015- **Chief Clinical Strategy Officer**, Dana-Farber Cancer Institute

Honors:

1978 White (European History) and Semler (Russian Studies) Prizes , Yale College
1983 Alpha Omega Alpha
1994 Wendell Rosse Award for Excellence in Teaching, Duke University School of Medicine
1996 R. Wayne Rundles Award for Excellence in Cancer Research, Duke University School of Medicine
2002 Claire W. and Richard P. Morse Research Award, Dana-Farber Cancer Institute
2006 Tisch Award for Outstanding Achievement, Dana-Farber Cancer Institute
2009 A. Clifford Barger Excellence in Mentoring Award, Harvard Medical School
2016 William McGuire Lecture and Award, San Antonio Breast Cancer Symposium

C. Contributions to Science

1. **Treatment of HER2+ Breast Cancer.** The treatment of HER2+ breast cancer has evolved over the past 20 years. The use of trastuzumab has improved survival in the adjuvant and metastatic settings, and multiple other targeted agents have been developed. I have led numerous trials in the adjuvant, neoadjuvant and metastatic settings. We conducted the first neoadjuvant trial of a trastuzumab-containing regimen and developed a new chemotherapy-trastuzumab regimen over 15 years ago that was widely used in the metastatic setting for over 10 years. Most notably, I developed and led a large phase II adjuvant trial that changed the standard of care for patients with stage I HER2+ breast cancer. Other research includes the treatment of HER2+ brain metastases (see below) and studies that have focused on novel drugs as well as the natural history of the disease.
    a. Burstein HJ, Harris LN, Gelman R, Lester SC, Nunes RA, Kaelin CM, Parker LM, Ellisen LW, Kuter I, Gadd MA, Christian RL, Kennedy PR, Borges VF, Bunnell CA, Younger J, Smith BL, Winer EP. Preoperative Therapy with Trastuzumab and Paclitaxel Followed by Sequential Adjuvant Doxorubicin/Cyclophosphamide for HER2 Overexpressing Stage II or III Breast Cancer. J Clin Oncol. 2003;21(1):46-53.. PMCID not needed
    b. Partridge AH, Gelber S, Piccart-Gebhart MJ, Focant F, Scullion M, Holmes E, Winer EP, Gelber RD. Effect of age on breast cancer outcomes in women with human epidermal growth factor receptor 2-positive breast cancer: results from a herceptin adjuvant trial. J Clin Oncol. 2013 Jul 20;31(21):2692-8. Epub 2013 Jun 10. PMCID not needed

c. Tolaney SM, Barry WT, Dang CT, Yardley DA, Moy B, Marcom PK, Albain KS, Rugo HS, Ellis M, Shapira I, Wolff AC, Carey LA, Overmoyer BA, Partridge AH, Guo H, Hudis CA, Krop IE, Burstein HJ, Winer EP. Adjuvant Paclitaxel and Trastuzumab for Node-Negative, HER2-Positive Breast Cancer. N Engl J Med. 2015 Jan 8;372(2):134-41. PMCID: PMC4313867

2. **Treatment of Triple Negative Breast Cancer.** Triple negative breast cancer accounts for only 10-15% of all cases of the disease, but it disproportionately affects younger women, women of African-American descent, and women who carry a deleterious BRCA1 mutation. Triple negative breast cancer is also responsible for a disproportionate number of breast cancer deaths. At present, the only available systemic treatment is chemotherapy. Over the past decade, I have conducted multiple trials in women with triple negative breast cancer with the goal of improving treatment options. These trials include a number of neoadjuvant studies as well as multiple trials in the metastatic setting. Almost all of these trials have either utilized a novel agent or a novel agent in combination with established therapy.
   a. Silver DP, Richardson AL, Eklund AC, Wang ZC, Szallasi Z, Li Q, Juul N, Leong CO, Calogrias D, Burainoh A, Fatima A, Gelman RS, Ryan PD, Tung NM, De Nicolo A, Ganesan S, Miron A, Colin C, Sgroi DC, Eillisen LW, Winer EP, Garber JE. Efficacy of Neoadjuvant Cisplatin in Triple-Negative Breast Cancer. J Clin Oncol. 2010, 27:1145-53. PMCID: PMC2834466
   b. Carey LA, Rugo HS, Marcom PK, Mayer EL, Esteva FJ, Ma CX, Liu MC, Storniolo AM, Rimawi MF, Forero-Torres A, Wolff AC, Hobday TJ, Ivanova A, Chiu WK, Ferraro M, Burrows E, Bernard PS, Hoadley KA, Perou CM, Winer EP. TBCRC 001: Randomized Phase II Study of Cetuximab in Combination with Carboplatin in Stage IV Triple-Negative Breast Cancer. J Clin Oncol. 134:1305-1313. Epub 4Jun 2012. PMCID: PMC3413275
   c. Balmaña J, Tung NM, Isakoff SJ, Graña B, Ryan PD, Saura C, Lowe ES, Frewer P, Winer E, Baselga J, Garber JE. Phase I Trial of Olaparib in Combination with Cisplatin for the Treatment of Patients with Advanced Breast, Ovarian and Other Solid Tumors. Ann Oncol. 2014 Aug;25(8):1656-63.. Epub 2014 May 14. PMCID not needed

3. **Treatment of Brain Metastases.** Brain metastases are a major source of morbidity in women with metastatic breast cancer, particularly those with HER2+ and triple negative disease. We were the first group to note the high incidence of brain metastases in women with HER2+ disease treated with trastuzumab. We subsequently found that women with triple negative breast cancer have a similarly high indigence of CNS disease. In a series of clinical trials, we have sought to develop treatments for patients with brain metastases. Our recent efforts have involved the development of PDX models in which resected human brain metastases are implanted in mouse brain. This effort involves a multidisciplinary collaboration between medical oncology, neuropathology, and translational scientists.
   a. Bendell JC, Domchek SM, Burstein HJ, Harris L, Younger J, Kuter K, Bunnell C, Rue M, Gelman R, Winer E. Central Nervous System Metastases in Women Who Receive Trastuzumab Based Therapy for Metastatic Breast Carcinoma. Cancer. 2003;97:2972-77. PMCID not needed
   b. Lin NU, Claus E, Sohl J, Razzak AR, Armaout A, Winer EP. Sites of Distant Recurrence and Clinical Outcomes in Patients with Metastatic Triple-Negative Breast Cancer: High Incidence of Central Nervous System Metastases. Cancer. 2008; 113:2638-45. PMCID: PMC2835546.
   c. Lin NU, Diéras V, Paul D, Lossignol D, Christodoulou C, Stemmler H, Roché H, Liu MC, Greil R, Ciruelos E, Loibl S, Gori S, Wardley A, Yardley D, Brufsky A, Blum JL, Rubin SD, Dharan B, Steplewski K, Zembryki D, Oliva C, Roychowdhury D, Paoletti P, Winer EP. Multicenter Phase II Study of Lapatinib in Patients with Brain Metastases from HER2+ Breast Cancer. Clin Cancer Res, 2009;15:1452-59. PMCID not needed
   d. Lin NU, Freedman RA, Ramakrishna N, Younger J, Storniolo AM, Bellon JR, Come SE, Gelman RS, Harris GJ, Henderson MA, Macdonald SM, Mahadevan A, Eisenberg E, Ligibel JA, Mayer EL, Moy B, Eichler AF, Winer EP. A phase I study of lapatinib with whole brain radiotherapy in patients with Human Epidermal Growth Factor Receptor 2 (HER2)-positive breast cancer brain metastases. Breast Cancer Res Treat. 2013 Nov;142(2):405-14. PMCID not needed

4. **Health Services and Psychosocial Research.** I have had an ongoing interest in the impact of breast cancer on a women's psychological health and quality of life. This interest was initially focus on the impact of high intensity therapy, such as high dose chemotherapy with autologous bone marrow transplantation, on a women's ability to function. My research has included evaluating the impact of a

diverse set of influences, including press coverage of breast cancer stories and provision of clinical trial results to participants, on a woman's psychological and psychosocial function. Similarly, I have worked with health services researchers to assess the impact of race, age, and socioeconomic status on breast cancer outcomes.

a. Partridge AH, Gelber S, Peppercorn J, Sampson E, Knudsen K, Laufer M, Rosenberg R, Przypyszny, M, Rein A, Winer EP. A Web-based Survey of Fertility Issues in Young Women with Breast Cancer. J Clin Oncol. 2004;22:4174-83. PMCID not needed
b. Peppercorn J, Herndon J 2nd, Kornblith AB, Peters W, Ahles T, Vredenburgh J, Schwartz G, Shpall E, Hurd DD, Holland J, Winer E. Quality of life among patients with Stage II and III breast carcinoma randomized to receive high-dose chemotherapy with autologous bone marrow support or intermediate-dose chemotherapy: results from Cancer and Leukemia Group B 9066. Cancer. 2005 Oct 15;104(8):1580-9. PMCID not needed.
c. Freedman RA, He Y, Winer EP, Keating NL. Racial/Ethnic Differences in Receipt of Timely Adjuvant Therapy for Older Women with Breast Cancer: Are Delays Influenced by the Hospitals where Patients Obtain Surgical Care? Health Serv Res. 2013 Oct;48(5):1669-83. Epub 2013 May 13. PMCID: PMC3796107

5. **Cooperative Group Research.** For over 10 years, I have been the co-chair of the Cancer and Leukemia Group B and Alliance breast cancer committees. In this context, I have led and/or played a key role in large phase III trials that have had a broad impact on clinical practice. These trials have included studies in the adjuvant, neoadjuvant, and metastatic settings and have included all the biologic subtypes of the disease.
   a. Berry DA, Cirrincione C, Henderson IC, Citron ML, Budman DR, Goldstein LJ, Martino S, Perez EA, Muss HB, Norton L, Hudis C, Winer EP. Estrogen-Receptor Status and Outcomes of Modern Chemotherapy for Patients with Node-Positive Breast Cancer. JAMA. 2006;295:1658-67. PMCID: PMC1459540
   b. Muss HB, Berry DA, Cirrincione CT, Theodoulou M, Mauer AM, Kornblith AB, Partridge AH, Dressler LG, Cohen HJ, Becker HP, Kartcheske PA, Wheeler JD, Burstein HJ, Mahmood AA, Magrinat G, Parker BA, Hart RD, Grenier D, Norton L, Hudis CA, Winer EP, for Cancer and Leukemia Group B. Adjuvant Chemotherapy in Older Women with Early Stage Breast Cancer. N Engl J Med. 2009 May 14;360(20):2055-65.. Erratum in: N Engl J Med. 2009 Oct 22;361(17):1714. Magrinat, Gutav [corrected to Magrinat, Gustav]. PMCID: PMC3082436
   c. Carey LA, Berry DA, Cirrincione CT, Barry WT, Pitcher BN, Harris LN, Ollila DW, Krop IE, Henry NL, Weckstein DJ, Anders CK, Singh B, Hoadley K, Iglesia M, Cheang M, Perou CM, Winer EP, Hudis CA. Molecular Heterogeneity and Response to Neoadjuvant Human Epidermal Growth Factor Receptor 2 Targeting in CALGB 40601, a Randomized Phase III Trial of Paclitaxel plus Trastuzumab with or without Lapatinib. J Clin Oncol. 2015 Nov 2. [Epub ahead of print]
   d. Sikov WM, Berry DA, Perou CM, Singh B, Cirrincione CT, Tolaney SM, Kuzma CS, Pluard TJ, Somlo G, Port ER, Golshan M, Bellon JR, Collyar D, Hahn OM, Carey LA, Hudis CA, Winer EP. Impact of the Addition of Carboplatin and/or Bevacizumab to Neoadjuvant Once-per-Week Paclitaxel Followed by Dose-Dense Doxorubicin and Cyclophosphamide on Pathologic Complete Response Rates in Stage II to III TNBC: CALGB 40603 (Alliance). J Clin Oncol. 2015 Jan 1;33(1):13-21.. Epub 2014 Aug 4. PMCID: PMC4268249.
   e. Rugo HS, Barry WT, Moreno-Aspitia A, Lyss AP, Cirrincione C, Leung E, Mayer EL, Naughton M, Toppmeyer D, Carey LA, Perez EA, Hudis C, Winer EP. Randomized Phase III Trial of Paclitaxel once per Week Compared with Nanoparticle Albumin-Bound Nab-Paclitaxel once per Week or Ixabepilone with Bevacizumab as First-Line Chemotherapy for Locally Recurrent or Metastatic Breast Cancer: CALGB 40502/NCCTG N063H (Alliance). J Clin Oncol. 2015 Jul 20;33(21):2361-9. Epub 2015 Jun 8. PMCID: PMC4500830.

Complete List of Published Work in MyBibliography:

- **http://www.ncbi.nlm.nih.gov/sites/myncbi/12wYSK6O6evA8/bibliography/41584805/public/?sort=date&direction=ascending.**

D. Research Support.

Ongoing Research Support

U58DP005385 (Partridge) 10/01/2014-9/29/2019
Centers for Disease Control and Prevention
Multiple Approaches to Increase Awareness and Support Among Young Women Diagnosed with Breast Cancer
The goal of this project is to enhance the structured supportive care, education and improve health outcomes in young women with breast cancer.
Role: Co-Investigator

SAB08-00001 (Winer) 01/01/2016-12/31/2016
Susan G. Komen for the Cure
Identifying clinically significant immune-related biomarkers in HR+ breast cancer
The specific aims of this project are 1) To assess gene and protein expression of immune-related biomarkers in breast biopsies from treatment-naïve hormone receptor-positive breast cancer patients. 2) To quantify changes in the immune microenvironment of hormone receptor-positive breast tumors following treatment with either chemotherapy or hormonal therapy. 3) To identify immune-related biomarkers that predict response to neoadjuvant therapy and longterm outcomes in hormone receptor-positive breast cancer.
Role: Principal Investigator

P30 CA06516 (Benz) 12/01/05 - 11/30/16
NIH/NCI
Dana-Farber/Harvard Cancer Center Support Grant
Dana Farber/Harvard Cancer Center (DF/HCC) is an inter-institutional research enterprise that unites the major clinical, population, and basic cancer research efforts of the Harvard medical and public health community. The primary goal of the Cancer Center is to promote collaborative interactions that will lead to new approaches to cancer prevention, diagnosis, and treatment.
Role: Co-Leader

(Lin and Winer) 10/01/15 – 09/30/16
Breast Cancer Research Foundation
Improving Therapeutic Options for Metastatic Breast Cancer
1) To evaluate and develop new treatment options for patients with breast cancer brain metastases, and 2) To identify resistance mechanisms operative in human breast cancers.
Role: Co-Investigator

1P50CA168504-01A1 (Winer) 09/17/13 – 07/31/18
NIH/NCI
Dana-Farber/ Harvard SPORE in Breast Cancer
The Dana-Farber/Harvard Cancer Center (DF/HCC) SPORE in Breast Cancer seeks to improve the prevention and treatment of breast cancer through four integrated, innovative, and highly translational Projects which span all of the major breast cancer subtypes and range in scope from basic and preclinical science to epidemiologic and clinical studies. The overarching goal of the DF/HCC SPORE in Breast Cancer is to promote translational research that can lead to tangible clinical benefit.
Role: SPORE Director

W81XWH-15-1-0268 (Winer) 09/15/15 – 09/14/20
Department of Defense
Randomized Trial of Asprin as Adjuvant Therapy for Node-Positive Breast Cancer
The aims of this project are to conduct a randomized placebo-controlled trial of aspirin (325 mg daily) among node-positive breast cancer survivors with invasive disease free survival as the primary endpoint, to assess adherence and toxicity of aspirin, and to create a longitudinal biospecimen and epidemiologic data repository. These will be key resources for future mechanistic studies with independent funding and for other researchers.
Role: Principal Investigator