

Susan Halabi, Ph.D.  
*CURRICULUM VITAE*  
April 20, 2020

**Primary academic appointment:** Professor (with Tenure)

**Primary academic department:** Department of Biostatistics and Bioinformatics

<u>Education</u>	<u>Institution</u>	<u>Date</u>	<u>Degree</u>
Graduate	The University of Texas Health Science Center at Houston, School of Public Health, Houston, Texas	1994	Ph.D in Biometry

**Scholarly Societies:**

American Statistical Association  
International Biometric Society  
Society for Clinical Trials  
American Society of Clinical Oncology

**Honors and Awards:**

1990-94 Good Neighbor Scholarship, Houston, Texas  
1994 Delta Omega, Honorary Society in Public Health  
2014 Fellow, Society of Clinical Trials  
2015 Fellow, American Statistical Association  
2018 Fellow, American Society of Medical Oncology  
2019 President-Elect, Society of Clinical Trials

**Professional training and academic career:**

<u>Institution</u>	<u>Position/Title</u>	<u>Dates</u>
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC	co-Chief Division of Biostatistics	2019-present
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC	Professor	2012-present
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC	Associate Professor	2005-2012

Alliance in Clinical Trials in Oncology	Lead Faculty Statistician	2014- 2017
Cancer and Leukemia Group B (CALGB), GU Committee, Durham, NC	Lead Faculty Statistician	1996-2014
Department of Surgery, Duke University Medical Center, Durham NC	Associate Professor	2010-2012
Division of Biometry, Community And Family Medicine, Duke University Medical Center, Durham NC	Assistant Professor	1997-2005
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC	Assistant Professor	07/00-02/05
Division of Biometry, Community And Family Medicine, Duke University Medical Center, Durham NC	Assistant Professor	1996-2000
Department of Biostatistics and Epidemiology, School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA	Adjunct Assistant Professor	1997-2001
Department of Biostatistics and Epidemiology, School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA	Assistant Professor	1994-1996
Department of Medicine, School of Medicine, Tulane University, New Orleans, LA	Adjunct Assistant Professor	1994-1996
Tulane Cancer Center Tulane University, New Orleans, LA	Assitant Director, Office of Clinical Research	1994-1996
Department of Epidemiology, MD Anderson Cancer Center, Houston, Texas	Pre-doctoral Fellow	1993-1994

**Patents:**

Biomarker Based Prognostic Model for Predicting Overall Survival in Patients with Metastatic Clear Cell Kidney Cancer (Int'l Patent Appln No PCT/US2016/016460 Appl# 4852-4365-44444)

## Publications:

### I. Refereed journals:

1. Khat M, **Halabi S**, Khudr A, and Der Kaloustian V (1986). Perception of consanguineous marriage and their genetic effects among a sample of couples from Beirut. *American Journal of Medical Genetics* 25:299-306.
2. Khat M and **Halabi S** (1986). Modernization and consanguineous marriages in Beirut. *Journal of Biosocial Sciences* 18:489-495.
3. Zurayk H, **Halabi S**, and Deeb M (1987). Measures of social class based on education for health studies in developing countries. *Journal of Epidemiology and Community Health* 41:173-179.
4. Armenian H, Lakkis N, Sibai A, and **Halabi S** (1988). Hospital visitors as controls. *American Journal of Epidemiology* 127:404-406.
5. Armenian HK, **Halabi S**, and Khat M (1989). The epidemiology of primary health problems in Beirut. *Journal of Epidemiology and Community Health* 43:316-319.
6. Vernon SW, Vogel VG, **Halabi S**, Jackson GL, Lundy RO, and Peters GN (1992). Breast cancer screening behaviors and attitudes in three racial/ethnic groups. *Cancer* 69:165-174.
7. Bondy ML, Vogel VG, **Halabi S**, and Lustbader E (1992). Identification of women at increased risk for breast cancer in a population-based screening program. *Cancer Epidemiology, Biomarkers & Prevention* 1:143-147.
8. **Halabi S**, Zurayk H, Awaida R, Darwish M, and Saab B (1992). Reliability and validity of self and proxy reporting of morbidity data: A case study from Beirut, Lebanon. *International Journal of Epidemiology* 3:607-612.
9. Bondy ML, Spitz MR, **Halabi S**, Fueger JJ, Vogel VG (1992). Low incidence of familial breast cancer among Hispanic women. *Cancer Causes and Control* 3:337-382.
10. Bondy ML, Spitz MR, **Halabi S**, Fueger JJ, Schantz SP, Sample D, Hsu TC (1993). Association between family history of cancer and mutagen sensitivity in upper aerodigestive tract cancer patients. *Cancer Epidemiology, Biomarkers & Prevention* 2:103-106.
11. Peters GN, Vogel VG, Evans WP, Bondy ML, **Halabi S**, Lord J, Laville EA, and the Texas Breast Screening Project Scientific Review Committee (1993). The Texas Breast Screening Project: I. Mammographic and clinical results. *Southern Medical Journal* 86:385-390.
12. Vogel VG, Bondy ML, **Halabi S**, Lord J, Laville EA, and the Texas Breast Screening Project Scientific Review Committee (1993). The Texas Breast Screening Project II. Demographics, risk profiles, and health practices of participants. *Southern Medical Journal* 86:391-396.

13. Spitz MR, Fueger JJ, **Halabi S**, Schantz P, Sample D, Hsu TC (1993). Mutagen sensitivity in upper aerodigestive tract cancer: A case-control analysis. *Cancer Epidemiology, Biomarkers & Prevention* 2:329-333.
14. Schustermann MA, Kroll SS, Reece GP, Miller MJ, Ainslie N, **Halabi S**, Balch CM (1993). Incidence of autoimmune disease in patients after breast reconstruction with silicone gel implants versus autogenous tissue. *Annals of Plastic Surgery* 31:1-6.
15. **Halabi S**, Vogel VG, Bondy ML, Vernon SW (1993). Recruiting older women for screening mammography. *Cancer Detection and Prevention* 17:359-365.
16. Vernon SW, Vogel VG, **Halabi S**, Bondy ML (1993). Factors associated with perceived risk of breast cancer. *Breast Cancer Research and Treatment* 28:137-144.
17. Bondy ML, Lustbader E, **Halabi S**, Ross E, Vogel VG (1994). Validation of a breast cancer risk assessment model with a positive family history. *Journal of the National Cancer Institute* 86:620-625.
18. Ji W, Qu G, Ye P, Zhang X, **Halabi S**, Ehrlich M (1995). Frequent detection of bcl-2/J<sub>H</sub> translocations in human blood and organ samples by a quantitative PCR assay. *Cancer Research* 55:2876-2882.
19. Pillai MR, **Halabi S**, McKalip A, Jayaprakash PG, Rajalekshmi TN, Krishnan Nair M, Herman B (1996). The presence of human papillomavirus 16/18 E6, p53 and Bcl-2 protein expression in cervicovaginal smears from patients with cervical cancer. *Cancer Epidemiology, Biomarkers & Prevention* 5:329-335.
20. Crane MM, Strom SS, **Halabi S**, Berman EL, Fueger JJ, Spitz MR (1996). Correlation between selected environmental exposures and karyotype in acute myelocytic leukemia. *Cancer Epidemiology, Biomarkers & Prevention* 5:639-644.
21. Robinson WR, **Halabi S**, Roberts A, Adams J (1997). Risk factors for margin involvement in specimens generated by LEEP excision of the cervix. *Journal of Gynecologic Techniques* 3:17-20.
22. Coughlin SS, **Halabi S**, Metayer C (1998). Barriers to cardiac transplantation in idiopathic dilated cardiomyopathy: The Washington DC dilated Cardiomyopathy Study. *Journal of National Medical Association* 90(6):342-348.
23. Bublej GJ, Carducci M, Dahut W, Dawson N, Daliani D, Eisenberger M, Figg WD, Freidlin B, **Halabi S**, Hudes G, Hussain M, Kaplan R, Myers C, Oh W, Petrylak DP, Reed E, Roth B, Sartor O, Scher H, Simons J, Sinibaldi V, Small EJ, Smith MR, Trump DL, Vollmer R, Wilding G (1999). Eligibility and response guidelines for phase II clinical trials in androgen independent prostate cancer: Recommendations from the PSA working group. *Journal of Clinical Oncology* 17:3461-3467.

24. Savarese DM, Taplin ME, **Halabi S**, Kreis W, Hars V, Vogelzand NJ (1999). A phase II study of docetaxel, estramustine, and low dose hydrocortisone in men with hormone refractory prostate cancer: Preliminary results of CALGB 9780. *Seminars in Oncology* 26:39-44.
25. Anreder MB, Merogi A, Freeman SM, **Halabi S**, Marrogi AJ (1999). P53, C-erbB2 and PCNA Status in benign, Proliferative and malignant ovarian surface epithelial neoplasms: A study of 75 cases. *Archives of Pathology and Laboratory Medicine* 123(4):310-316.
26. Johnson ES, **Halabi S**, Netto G, Gladen B, Lucier G, Bechtold W, Henderson R (1999). Detection of low level benzene exposure in supermarket wrappers by urinary muconic acid. *Biomarkers* 4:106-117.
27. Rimer BK, **Halabi S**, Lipkus IM, Strigo TS, Crawford Y, Purcell C (1999). Confusion about mammography: prevalence and consequences. *Journal of Women's Health and Gender-Based Medicine* 8:509-520.
28. Kantoff PW, **Halabi S**, Conaway MR, Picus J, Hars V, Trump D, Winer E, Vogelzang NJ (1999). Hydrocortisone with or without mitoxantrone in men with hormone refractory prostate cancer: The results of CALGB 9182. *Journal of Clinical Oncology* 17:2506-2513.
29. Burns CP, **Halabi S**, Clamon GH, Hars V, Wagner BA, Hohl RJ, Lester E, Kirshner JJ, Vinciguerra V, Paskett E (1999). Phase I clinical study of fish oil fatty acid capsules for patients with cancer cachexia: Cancer and Leukemia Group B Study 9473. *Clinical Cancer Research* 5:3942-3947.
30. Bastian LA, McBride CM, **Halabi S**, Fish LJ, Skinner CS, Bosworth HA, Kaplan EB, Rimer BK, Siegler IC (1999). Attitudes and knowledge associated with being undecided about Hormone replacement therapy: Results from a community sample. *Women's Health Issues* 9:330-337.
31. Schildkraut JM, **Halabi S**, Bastos E, Marchbanks PA, McDonald JA, Berchuck A (2000). Prognostic significance of p53 overexpression in epithelial ovarian cancers diagnosed in women before age 55: A population-based study. *Obstetrics & Gynecology* 95:119-127.
32. Lipkus IM, Rimer BK, **Halabi S**, Strigo TS (2000). Can tailored interventions increase mammography use among HMO women? *American Journal of Preventive Medicine* 18:1-10.
33. Dawson NA, Conaway MR, **Halabi S**, Small EJ, Lake D, Winer EP, Cooper MR, Woliver TB, Ernstoff MS, Vogelzang NJ (2000). A randomized study comparing standard versus moderately high dose megestrol acetate in advanced prostate cancer: CALGB 9181. *Cancer* 88:825-834.
34. McBride CM, **Halabi S**, Bepler G, Lyna P, McIntyre L, Lipkus I, Albright J, O' Briant K (2000). Maximizing the motivational impact of feedback of lung cancer susceptibility on smokers' desire to quit. *Journal of Health Communication* 5: 229-241.

35. Lipkus IM, **Halabi S**, Strigo TS, Rimer BK (2000). The impact of abnormal mammograms on psychosocial outcomes and subsequent screening. *Psycho-Oncology* 9:402-410.
36. **Halabi S**, Skinner CS, Samsa GP, Strigo TS, Crawford Y, Rimer BK (2000). Factors associated with repeat mammography screening. *Journal of Family Practice* 49:1104-1112.
37. Sandler RS, **Halabi S**, Kaplan EB, Baron JA, Paskett ED, Petrelli NJ (2001). Use of vitamins, minerals and nutritional supplements by participants in a chemoprevention trial. *Cancer* 91:1040-1045.
38. Bok RA, **Halabi S**, Fei DT, Rodrigues CR, Hayes DF, Vogelzang NJ, Kantoff PW, Shuman MA, Small EJ (2001). Vascular endothelial growth factor and basic fibroblast growth factor urine levels as predictors of outcome in hormone refractory prostate cancer: A CALGB study. *Cancer Research* 61(6):2533-2536.
39. Savarese DM, **Halabi S**, Hars V, Akerley W, Godley P, Hussain A, Small E, Vogelzang NJ (2001). Phase II study of docetaxel, estramustine, and low-dose hydrocortisone in men with hormone-refractory prostate cancer: A final report of CALGB 9780. *Journal of Clinical Oncology* 19:2509-2516.
40. Rimer BK, **Halabi S**, Skinner CS, Kaplan EB, Crawford Y, Samsa GP, Strigo TS, Lipkus IM (2001). The short-term impact of a mammography decision-making intervention for women. *Patient Education and Counseling* 43:269-285.
41. Schildkraut J, Cooper G, **Halabi S**, Whittemore A, Hartge P, Berchuck A (2001). Age at natural menopause and the risk of developing invasive epithelial ovarian cancer. *Obstetrics & Gynecology* 98:85-90.
42. Bastian LA, Lipkus IM, Kuchibhatla MN, Haoling HW, **Halabi S**, Ryan PD, Skinner CS, Rimer BK (2001). Interest in chemoprevention for breast cancer: Results from a community sample. *Archives of Internal Medicine* 161:1565-1688.
43. George DJ, **Halabi S**, Shepard TF, Vogelzang NJ, Hayes DF, Small EJ, Kantoff PW (2001). Prognostic significance of plasma vascular endothelial growth factor (VEGF) levels in patients with hormone refractory prostate cancer: A CALGB study. *Cancer Clinical Research* 7:1932-1936.
44. Kantoff PW, **Halabi S**, Farmer DA, Hayes DF, Vogelzang NA, Small EJ (2001). Prognostic significance of reverse transcriptase polymerase chain reaction (RT-PCR) for prostate specific antigen (PSA) in men with androgen independent prostate cancer. *Journal of Clinical Oncology* 19:3025-3028.
45. **Halabi S**, Conaway MR, Small EJ, Vogelzang NJ, Dawson NA (2001). Serum prostate specific antigen as a predictor of survival in prostate cancer patients treated with second-line hormonal therapy (CALGB 9181). *The Prostate Journal* 3:18-25.

46. Levine EG, **Halabi S**, Roberts JD, Kaplan EB, Rago R, Atkins JN, Vogelzang NJ (2002). Higher doses of mitoxantrone among men with hormone refractory prostate cancer: A Cancer and Leukemia Group B study. *Cancer* 94:665-672.
47. Rimer BR, **Halabi S**, Skinner CS, Lipkus IM, Strigo TS, Kaplan EB, Glassman B, Farrell D, Samsa GP (2002). Effects of a mammography decision-making intervention at 12 and 24 months. *American Journal of Preventive Medicine* 22:247-257.
48. McBride CM, Bastian LA, **Halabi S**, Fish L, Lipkus IM, Bosworth HB, Rimer BK, Siegler I (2002). Efficacy of a tailored intervention to aid decision-making about hormone replacement therapy. *American Journal of Public Health* 92:1112-1114.
49. Small EJ, **Halabi S**, Rattain M, Rosner G, Stadler W, Palchak D, Marshall E, Rago R, Hars V, Wilding G, Petrylak D, Vogelzang NJ (2002). Randomized study of three different doses of suramin administered with a fixed dosing schedule in patients with advanced prostate cancer: Results of Intergroup 0159, Cancer and Leukemia Group B 9480. *Journal of Clinical Oncology* 20:3369-3375.
50. Moorman PG, Schildkraut JM, Calingaert B, Vine M, **Halabi S**, Berchuck A (2002). Ovulation and ovarian cancer: A comparison of two methods for calculating lifetime ovulatory cycles. *Cancer Causes and Control* 13:807-811.
51. **Halabi S**, Small EJ, Hayes DF, Vogelzang NJ, Kantoff PW (2003). Prognostic significance of reverse transcriptase polymerase chain reaction for prostate-specific antigen in metastatic prostate cancer. *Journal of Clinical Oncology* 21:490-495.
52. Sandler RS, **Halabi S**, Baron JA, Budinger S, Paskett E, Kereszates R, Petrelli N, Pipsa JM, Karp DD, Loprinzi CL, Steinback G, Schilsky R (2003). A randomized trial of aspirin to prevent colorectal adenomas in patients with previous colorectal cancer. *New England Journal of Medicine* 348:883-890.
53. **Halabi S**, Small EJ, Kantoff PW, Kattan MW, Kaplan EB, Dawson NA, Levine EG, Blumenstien BA, Vogelzang NJ (2003). Prognostic model for predicting survival in men with hormone-refractory metastatic prostate cancer. *Journal of Clinical Oncology* 21:1232-1237.
54. Small EJ, **Halabi S**, Dalbagni G, Pruthi R, Philips G, Edelman M, Bajorin D (2003). Overview of bladder cancer trials in the Cancer and Leukemia Group B. *Cancer* 97(8 Suppl):2090-2098.
55. **Halabi S**, Wun CC, Davis BR (2003). Analysis of survival data with missing measurements of a time-dependent binary covariate. *Journal of Biopharmaceutical Statistics* 13:253-270.
56. Lancaster JM, Wenham RM, **Halabi S**, Calingaert B, Marks JR, Moorman PG, Bentley RC, Berchuck A, Schildkraut JM (2003). No relationship between ovarian cancer risk and progesterone receptor gene polymorphism in a population-based, case-control study in North Carolina. *Cancer Epidemiology, Biomarkers & Prevention* 12:226-227.

57. Taplin, ME, Rajeshkumar B, **Halabi S**, Werner CP, Woda B A, Picus J, Stadler W, Hayes DF, Kantoff PW, Vogelzang NJ, Small EJ (2003). Androgen receptor mutations in androgen-independent prostate cancer: Cancer and Leukemia Group B Study 9663. *Journal of Clinical Oncology* 21:2673-2678.
58. Oh W, **Halabi S**, Kelly WK, Werner C, Godley PA, Vogelzang NJ, Small EJ (2003). A phase II study of estramustine, docetaxel and carboplatin with G-CSF support in patients with hormone refractory prostate cancer: Cancer and Leukemia Group B 99813. *Cancer* 98:2592-2598.
59. Sandler RS, **Halabi S**, Baron JA, Budinger S, Paskett E, Kereszates R, Petrelli N, Pipsa JM, Karp DD, Loprinzi CL, Steinback G, Schilsky R (2003). A randomized controlled trial of aspirin to prevent colorectal adenomas in patients with previous colorectal cancer. *Obstetrical and Gynecological Survey* 58:539-541.
60. Scher HI, Eisenberger M, D'Amico AV, **Halabi S**, Small EJ, Morris M, Kattan MW, Roach M, Kantoff P, Pienta KJ, Michael A, Carducci MA, Slovin SF, Heller G, Kelly WK, Lange PH, Petrylak D, Berg W, Wilding G, Moul JW, Partin AN, Logothetis C, Soule HR (2004). Eligibility and outcomes reporting guidelines for clinical trials for patients in the state of a rising PSA: Recommendations from the prostate-specific antigen working group. *Journal of Clinical Oncology* 22:537-556.
61. Small EJ, **Halabi S**, Dawson NA, Stadler WM, Rini BI, Picus J, Gable P, Torti F, Kaplan E, Vogelzang NJ (2004). A phase III trial of antiandrogen withdrawal alone or in combination with ketoconazole in androgen-independent prostate cancer patients: Results of CALGB 9583. *Journal of Clinical Oncology* 22:1025-1033.
62. **Halabi S**, Singh B (2004). Sample size determination for comparing several survival curves with unequal allocations. *Statistics in Medicine* 23:1793-1815.
63. Rini BI, **Halabi S**, Taylor S, Small EJ, Schilsky RL (2004). Cancer and Leukemia Group B 90206: A randomized phase III trial of interferon-alpha or interferon-alpha plus anti-vascular endothelial growth factor antibody (bevacizumab) in metastatic renal cell carcinoma. *Clinical Cancer Research* 10:2584-2586.
64. Burns SP, **Halabi S**, Clamon G, Kaplan E, Hohl RJ, Atkins JN, Schwartz MA, Wagner BA, Paskett E (2004). Phase II study of high-dose fish oil capsules for patients with cancer cachexia: A Cancer and Leukemia Group B study. *Cancer* 101:370-378.
65. **Halabi S**, Small EJ, Vogelzang NJ, Barrier RC, George SL, Gilligan TD (2004). Impact of race on survival in men with metastatic hormone refractory prostate cancer. *Urology* 64:212-217.
66. Amin A, **Halabi S**, Glemann EP, Stadler W, Vogelzang N, Small EJ (2004). 9-Nitrocmtptothecin as second line chemotherapy for men with progressive, metastatic, hormone refractory prostate cancer: results of the CALGB 99901. *Urologic Oncology* 22:398-403.



67. Berchuck A, Schildkraut JM, Wenham RM, Calingaert B, Ali A, Henriott A, **Halabi S**, Rodriguez GC, Gertig D, Purdie DM, Kelemen L, Spurdle AB, Marks J, Chenevix-Trench G (2004). Progesterone receptor promoter +331A polymorphism is associated with a reduced risk of endometrioid and clear cell ovarian cancers. *Cancer Epidemiology, Biomarkers & Prevention* 13:2141-2171.
68. George DJ, **Halabi S**, Shepard TF, Sanford B, Vogelzang NJ, Small EJ, Kantoff PW (2005). The prognostic significance of plasma interleukin-6 (IL-6) levels in patients with metastatic hormone-refractory prostate cancer: Results from CALGB 9480. *Clinical Cancer Research* 11:1815-1820.
69. Moorman PG, Berchuck A, Calingaert B, **Halabi S**, Schildkraut JM (2005). Antidepressant medication use and risk of ovarian cancer. *Obstetrics and Gynecology* 105:725-730.
70. Spillman MA, Schildkraut JM, **Halabi S**, Moorman P, Calingaert B, Bentley RC, Marks JR, Murphy S, Berchuck A (2005). Transforming growth factor beta receptor I polyalanine repeat polymorphism does not increase ovarian cancer risk. *Gynecologic Oncology* 97:543-549.
71. Moorman PG, Schildkraut JM, Calingaert B, **Halabi S**, Berchuck A. Menopausal hormones and risk of ovarian cancer (2005). *American Journal of Obstetrics and Gynecology* 193:76-82.
72. Taplin ME, George DJ, **Halabi S**, Sanford B, Febbo PG, Hennessy KT, Mihos CG, Vogelzang NJ, Small EJ, Kantoff PW (2005). The prognostic significance of plasma chromogranin a levels in hormone-refractory prostate cancer patients treated on Cancer and Leukemia Group B (CALGB) 9480. *Urology* 66:386-391.
73. Hoyo C, Berchuck A, **Halabi S**, Bentley R, Moorman P, Calingaert B, Schildkraut J (2005). Anthropometric measurements and epithelial ovarian cancer risk in African American and white women. *Cancer Causes and Control* 16:955-963.
74. Ross R, **Halabi S**, Rajeshkumar B, Woda B, Vogelzang NJ, Small EJ, Taplin ME, Kantoff PW (2005). Predictors of prostate cancer tissue acquisition by an undirected core bone marrow biopsy in metastatic castration resistant prostate cancer - A cancer and leukemia group B study. *Clinical Cancer Research* 11:8109-8113.
75. Schildkraut JM, Moorman PG, **Halabi S**, Calingaert B, Marks JR, Berchuck A (2006). Analgesic drug use and risk of ovarian cancer. *Epidemiology* 17:104-107.
76. Humphrey PA, **Halabi S**, Picus J, Sanford B, Vogelzang NJ, Small EJ, Kantoff PW (2006). The prognostic significance of plasma scatter factor/hepatocyte growth factor levels in patients with metastatic hormone-refractory prostate cancer: Results from CALGB 150005/9480. *Clinical Genitourinary Cancer* 4:269-274.
77. **Halabi S**, Vogelzang NJ, Ou SS, Kelly WK, Small EJ (2006). Clinical outcomes by age in men with hormone refractory prostate cancer: A pooled analysis of eight Cancer and Leukemia Group B (CALGB) Studies. *Journal of Urology* 176:81-86.

78. Rini B, **Halabi S**, Barrier R, Margolin KA, Avigan D, Logan T, Stadler WM, McCarthy PL, Linker CA, Small EJ (2006). Adoptive immunotherapy by allogeneic stem cell transplantation for metastatic renal cell carcinoma: A CALGB intergroup phase II study. *Biology of Blood and Marrow Transplantation* 12:778-785.
79. Stadler W, **Halabi S**, Rini B, Ernstoff MS, Davila E, Picus J, Barrier R, Small E (2006). A phase II study of gemcitabine and capecitabine in metastatic renal cancer: A report of Cancer and Leukemia Group B protocol 90008. *Cancer* 107:1273-1279.
80. **Halabi S**, Vogelzang NJ, Ou SS, Small EJ (2007). The impact of prior radical prostatectomy in men with metastatic castration-recurrent prostate cancer: A pooled analysis of nine CALGB trials. *Journal of Urology* 177:531-534.
81. Schildkraut JM, Murphy SK, Palmieri RT, Iversen E, Moorman PG, Huang S, **Halabi S**, Calingaert B, Gusberg A, Marks J, Berchuck A (2007). Trinucleotide repeat polymorphisms in the androgen receptor gene and risk of ovarian cancer. *Cancer Epidemiology Biomarkers and Prevention* 16:473-80.
82. Ryan CJ, **Halabi S**, Ou SS, Vogelzang NJ, Kantoff P, Small EJ (2007). Adrenal androgen levels as predictors of outcome in prostate cancer patients treated with ketoconazole plus antiandrogen withdrawal: Results from a Cancer and Leukemia B Study. *Clinical Cancer Research* 13:2030-7.
83. Kyle RA, Yee GC, Somerfield MR, Flynn PJ, **Halabi S**, Jagannath S, Orlovski RZ, Roodman DG, Twilde P, Anderson K (2007). American Society of Clinical Oncology 2007 clinical practice guideline update on the role of bisphosphonates in multiple myeloma. *Journal of Clinical Oncology* 25:2464-72.
84. **Halabi S**, Ou SS, Vogelzang NJ, Small EJ (2007). Inverse relationship between body mass index and clinical outcomes in men with advanced castration-recurrent prostate cancer. *Cancer* 110:1478-84.
85. **Halabi S** (2008). Statistical considerations for the design and analysis of phase III clinical trials in prostate cancer. *Urologic Oncology* 26:300-307.
86. Philips GK, **Halabi S**, Sanford BL, Bajorin D, Small EJ (2008). A phase II trial of cisplatin, fixed dose-rate gemcitabine and gefitinib for advanced urothelial tract carcinoma: results of the Cancer and Leukemia Group B 90102. *British Journal of Urology International*. 101:20-25.
87. Kim S, Keku TO, Martin C, Galanko J, Woosley JT, Schroeder JC, Satia JA, **Halabi S**, Sandler RS (2008). Circulating levels of inflammatory cytokines and risk of colorectal adenomas. *Cancer Research* 68:323-328.
88. Garmey EG, Sartor O, **Halabi S**, Vogelzang NJ (2008). Second-line chemotherapy for advanced hormone-refractory prostate cancer. *Clinical Advances in Hematology and Oncology* 6: 118-132.

89. Scher HI, **Halabi S**, Tannock I, Morris M, Sternberg CN, Carducci MA, Eisenberger MA, Higano C, Bubley GJ, Driecer R, Petrylak D, Kantoff P, Basch E, Kelly WK, Figg WD, Small EJ, Beer TM, Wilding G, Martin A, Hussain M (2008). Design and endpoints of clinical trials for Patients with Progressive Prostate Cancer and Castrate levels of testosterone: Recommendations of the Prostate Cancer Clinical Trials Working Group (PCWG2). *Journal of Clinical Oncology* 26:1148-59.
90. **Halabi S**, Vogelzang NJ, Kornblith AB, Ou SS, Kantoff PW, Dawson NA, Small EJ (2008). Pain predicts overall survival in men with metastatic castrate refractory prostate cancer (CRPC). *Journal of Clinical Oncology* 26:2544-9.
91. Singh B, **Halabi S**, Schell M (2008). Sample size selection in clinical trials when population means are subject to a partial order. *Journal of Applied Statistics* 35: 583-600.
92. Schildkraut JM, Moorman PG, Bland A, **Halabi S**, Calingaert B, Whitaker R, Lee PS, Elkins-Williams T, Bentley RC, Marks J, Berchuck A (2008). Cyclin E overexpression in epithelial ovarian cancer characterizes an etiologic subgroup. *Cancer Epidemiology Biomarkers Prevention* 17:585-93.
93. D'Amico AV, **Halabi S**, Tempany C, Titelbaum D, Philips GK, Loffredo M, McMahon E, Sanford B, Vogelzang NJ, Small EJ (2008). Tumor volume changes on 1.5 tesla endorectal MRI during neoadjuvant androgen suppression therapy for higher-risk prostate cancer and recurrence in men treated using radiation therapy results of the phase II CALGB 9682 study. *International Journal of Radiation Oncology, Biology, Physics* 71:9-15.
94. D'Amico AV, **Halabi S**, Vollmer R, Loffredo M, McMahon E, Sanford B, Archer L, Vogelzang NJ, Small EJ (2008). P53 protein expression status and recurrence in men treated with radiation and androgen suppression therapy for higher-risk prostate cancer : A prospective phase II Cancer and Leukemia Group B study (CALGB 9682). *Urology* 71:933-7.
95. Rosenberg JE, **Halabi S**, Sanford BL, Himelstein AL, Atkins JN, Hohl RJ, Millard F, Bajorin DF, Small EJ (2008). Phase II study of bortezomib in patients with previously treated advanced urothelial tract transitional cell carcinoma: CALGB 90207. *Annals of Oncology* 19:946-50.
96. Moorman PG, Calingaert B, Palmieri RT, Iversen ES, Bentley RC, **Halabi S**, Berchuck A, Schildkraut JM (2008). Hormonal risk factors for ovarian cancer in premenopausal and postmenopausal women. *American Journal of Epidemiology* 167:1059-69.
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185. **Halabi S**, Li C, Luo S (2019). Developing and Validating Risk Assessment Models of Clinical Outcomes in Modern Oncology. *JCO Precis Oncol* 3. doi: 10.1200/PO.19.00068.

186. George DJ, **Halabi S**, Healy P, Barak I, Winters C, Anand M, Wilder R, Klein M, Martinez E, Nixon AB, Harrison MR, Szmulewitz R, Armstrong AJ (2019). Phase 1b trial of docetaxel, prednisone, and pazopanib in men with metastatic castration-resistant prostate cancer. *Prostate* 79(15):1752-1761. doi: 10.1002/pros.23899.
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Management of Patients with Advanced Prostate Cancer: Report of the Advanced Prostate Cancer Consensus Conference 2019. *Eur Urol* doi: 10.1016/j.eururo.2020.01.012.

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198. Ryan CJ, Dutta S, Kelly WK, Middleberg R, Russell C, Small EJ, Morris MJ, Taplin ME, **Halabi S** Androgens and Overall Survival in Metastatic Castration-Resistant Prostate Cancer Patients Treated with Docetaxel, Results from CALGB 90401 (Alliance). *In press* (Clinical Genitourinary Cancer).

199. Xie W, Regan MR, Buyse M, **Halabi S**, Kantoff PW, Sartor O, Soule H, et al. Event-Free Survival, a PSABased Composite Endpoint, is Not a Surrogate for Overall Survival in Men with Localized Prostate Cancer Treated with Radiation. *In press* (Journal of Clinical Oncology).

## Editorials

Armstrong AJ, **Halabi S** (2015). Making progress on progression in metastatic prostate cancer. *Journal of Clinical Oncology*. Epub ahead of time10.1200/JCO.2014.59.4283

## Invited Non-peered Reviewed Articles

1) Small EJ, **Halabi S**, Kantoff P, D'Amico A, Stadler W, Kelly WK, Mohler J, Bajorin D, Vogelzang NJ (2006). Activities and accomplishments of the Cancer and Leukemia Group B Genitourinary Committee. *Clinical Cancer Research* 12:3596s-600s.

2) Fitzpatrick JM, Sternberg CN, Saad F, Extermann M, Caffo O, **Halabi S**, Kramer G, Oudard S, de Wit R (2009). Treatment decisions for advanced genitourinary cancers: From symptoms to risk assessment. *European Urology Supplements* 8: 738-746.

### **Chapters in Books:**

1) Wodnicki P, Lockett S, Pillai R, **Halabi S**, McKalip A, Herman B (1996). Automated image microscopy in Fluorescence Imaging Spectroscopy and Microscopy, editors Herman B and Wang XF. John Wiley & Sons, Inc., New York.

2) **Halabi S**. Design considerations of randomized phase III trials in oncology in Encyclopedia of Medical Decision Making, editor Michael Kattan. Sage Publications, Inc., Thousand Oaks, CA 2009.

3) **Halabi S**, Kelly WK. Introduction to a clinical trial. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, New York, NY, 2010.

4) **Halabi S**. Statistical considerations for assessing prognostic factors in cancer. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, New York, NY, 2010.

5) **Halabi S**. Multiple arm trials. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, New York, NY, 2010.

6) **Halabi S**, Pi, L. Statistical considerations for developing and validating prognostic models of Clinical Outcomes. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, 2<sup>nd</sup> Edition, New York, NY, 2018.

7) Wu Y, **Halabi, S**. Interval Censoring In *Textbook of Clinical Trials in Oncology: A Statistical Perspective*, edited by Susan Halabi and Stefan Michiels. Boca Raton, FL, CRC Press, 2019.

8) **Halabi S**, Pi L, Lin CY. Developing and Validating Prognostic Models of Clinical Outcomes. In *Textbook of Clinical Trials in Oncology: A Statistical Perspective*, edited by Susan Halabi and Stefan Michiels. Boca Raton, FL, CRC Press, 2019.

### **Edited Books**

Kelly WK, **Halabi S**. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*. Demos Medical Publishing, New York, NY, 2010.

Kelly WK, **Halabi S**. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*. Demos Medical Publishing, 2<sup>nd</sup> Edition, New York, NY, 2018.

**Halabi S**, Michiels S. Textbook of Clinical Trials in Oncology. Chapman & Hall/CRC Press, London: UK, 2019.

## Others

### A. Letters to the Editor:

1. Schildkraut JM, Bastos E, **Halabi S**, Berchuck A (1997). Relationship between lifetime ovulatory cycles and overexpression of mutant p53 in epithelial ovarian cancer. *Journal of the National Cancer Institute*, 89:1726-1727.
2. Demark-Wahnefried W, **Halabi S**, Paulson DF (1998). Serum androgens: associations with prostate cancer risk and hair patterning. *Journal of Andrology*, 19:631.
3. **Halabi S**, Small EJ, Vogelzang NJ (2005). An elevated body mass index predicts for longer overall survival duration in men with metastatic hormone refractory prostate cancer (HRPC). *Journal of Clinical Oncology* 23:2434-2435.
4. Scher HI, **Halabi S**, Tannock I, Morris M, Sternberg CN, Carducci MA, Eisenberger MA, Higano C, Bubley GJ, Driecer R, Petrylak D, Kantoff P, Basch E, Kelly WK, Figg WD, Small EJ, Beer TM, Wilding G, Martin A, Hussain M (2008). Reply to trial design for metastatic castration-resistant prostate cancer *Journal of Clinical Oncology* 26:3648-9.
5. **Halabi S**, Vogelzang NJ, Kornblith AB, Ou SS, Kantoff PW, Dawson NA, Small EJ (2008). Reply to "Pain interference items predication of cancer patients' survival is not the same as an evidence for that pain intensity is a survival predictor. *Journal of Clinical Oncology* 26: 4216-7.
6. Stadler WM, Phillips G, George DJ, **Halabi S**, Small E (2010). Bevacizumab and Everolimus in Renal Cancer: A rational way forward. *Journal of Clinical Oncology* 28:E692-3.
7. Armstrong AJ, George DJ, **Halabi S** (2013). Reply to Prognostic and predictive markers in metastatic renal cell carcinoma. *Journal of Clinical Oncology* 31(7):972-3.
8. Smith MR, **Halabi S**, Small EJ (2014). Reply to F. Valcamonico et al. *Journal of Clinical Oncology* 201 [Epub ahead of print]
9. **Halabi S**, Rini R, Escudier B, Stadler WM, Small EJ (2015). Reply to Progression-free survival: Does a correlation with survival justify its role as a surrogate clinical endpoint? *Cancer* 121(11):1906.
10. Choueiri TK, **Halabi S**, Morris MJ, George D. Reply to B. Rini et al and S. Buti et al. *J Clin Oncol*. 2017 Jun 1;35(16):1859-1860. doi: 10.1200/JCO.2017.72.2629.
10. Choueiri TK, **Halabi S**, Morris MJ, George D (2017). Reply to B. Rini et al and S. Buti et al. *J Clin Oncol*. 2017 Jun 1;35(16):1859-1860. doi: 10.1200/JCO.2017.72.2629.



11. Armstrong AJ, **Halabi S**, Luo J, Nanus DM, Scher HI, Antonarakis ES, George DJ (2019). Reply to L. Dirix, B. De Laere et al, and A. Sharp et al. *J Clin Oncol.* 37(24):2184-2186. doi: 10.1200/JCO.19.01230.

### **Selected Invited and Contributed Talks**

Halabi S. Validation of the Mitch Gail breast cancer risk model [(Invited) Presented at Boston University, February 1994].

Halabi S. Validation of the Gail breast cancer risk model [(Invited) Presented at Department of Biostatistics and Epidemiology, Memorial Sloan Kettering Cancer Center, NY, March 1994].

Halabi S. A Computer Program for Generating the Survival Distribution of a Cox Regression Model with a Time-Dependent Covariate [Presented at the International Biometric Society Eastern North American Region Annual Meeting, Richmond, VA, March 1995].

Halabi S. Validation of the Gail breast cancer risk model [(Invited) Presented at Community and Family Medicine, Duke University, Durham, NC, June 1996].

Halabi S. Analysis of Survival Data with Missing Measurements of a Binary Time-Dependent Covariate [Presented at the Presented at the International Biometric Society Eastern North American Region Annual Meeting, Chicago, IL, March 2000].

Halabi S. Results of CALGB 9480 (SWOG 9452, ECOG C9480, Intergroup 0159): A Phase III Trial of Three Different Doses of Suramin for the Treatment of Hormone Refractory Prostate Cancer (HRPC) [Presented at the American Society of Clinical Oncology Annual Meeting, New Orleans, LA, June 2000].

Halabi S. Innovative Designs in Phase II Oncology Clinical Trials. [(Invited) Presented at the Henry Ford System, Detroit, MI, October 2002].

Halabi S. Sample Size Determination for Comparing Several Survival Curves With Unequal Allocations [(Invited) Presented at the International Biometric Society Eastern North American Region Annual Meeting, Tampa, FL, March 2003].

Halabi S. The Impact of Age on Clinical Outcomes in Men with Hormone Refractory Prostate Cancer (HRPC) [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV, October 2004].

Halabi S. Sample Size Calculation for Longitudinal Data under Missing at Random (MAR). [Presented at the International Biometric Society Eastern North American Region Annual Meeting, Austin, TX, March 2005].

Halabi S. Implications in the Choice of Primary Endpoint and Alpha Allocation: A Statistician's Perspective. [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV, October 2005].

Halabi S. Sample Size Determination for Comparing Several Survival Curves with unequal allocations. [(Invited) Presented at the Cleveland Clinic Foundation, Cleveland, OH, December 2005].

Halabi S. On Sample Size Selection in Clinical trials With Both Accrual and Follow-up Periods for Comparing Several treatment Groups [(Invited) Presented at the Moffitt Cancer Center, Tampa, FL, March 2006].

Halabi S. Some Thoughts on Progression-Free Survival. [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV October 2006].

Halabi S. Adjustment on the Type I Error Rate for a Clinical Trial that Monitors for both an Intermediate and Primary Endpoints. [Presented at the Society of Clinical Trials Annual Meeting, Montreal, Canada, May 2007].

Halabi S. A Novel Intermediate Endpoint for Predicting Overall Survival in Men with Metastatic Castration-Recurrent Prostate Cancer (CRPC): An Analysis of nine CALGB Studies [Presented at the DOD Prostate Impact Meeting, Atlanta, GA, September 2007].

Halabi S. Challenges and Opportunities: Progression-Free Survival as an Endpoint in Phase III Clinical Trials. [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV, October 2007].

Halabi S. Predicting Overall Survival in Men with Castration-Resistant Prostate Cancer (CRPC). [(Invited) Plenary Presentation at the 1<sup>th</sup> Interactive Genitourinary Cancer Conference (IGUCC), Advances in Prostate Cancer: Lisbon, March 2009].

Halabi S. Two New Residuals In Survival Analysis With Full Likelihood Approach Using Proportional Hazards Model [Presented at the International Society of Clinical Biostatistics, Prague, August 2009].

Moser B, Halabi S. Estimation and testing of the relative risk of disease in retrospective case-control studies with a set of  $k$  matched controls per case. [Presented at the International Biometric Society Eastern North American Region Annual Meeting, New Orleans, LA, March 2010].

Halabi S. Prostate Cancer Clinical Trials: The Statistician's Perspective [(Invited) Presented at Thomas Jefferson University, Philadelphia, PA, March 2011].

Halabi S. Estimation and testing of the relative risk of disease in retrospective case-control studies with a set of  $k$  matched controls per case. [(Invited) Presented at Thomas Jefferson University, Philadelphia, PA, March 2011].

Halabi S. Enrichment Trials: Fact or Fiction? [(Invited) Presented at the Society of Clinical Trials Annual Meeting, Vancouver, Canada, May 2011].

Halabi S. Opportunities and Challenges in the Design and Implementation of Enrichment Trials. [(Invited) Presented at the Statistical Symposium Alliance Spring Meeting, Boston, MA, June 2011].

Halabi S. Debate on Prognostic models are a valuable tool for guiding treatment decisions in prostate cancer. [(Invited) Presented at the 4<sup>th</sup> Interactive Genitourinary Cancer Conference (IGUCC), Advances in Prostate Cancer: Integrating New Strategies in Clinical Practice, Prague, March 2012].

Halabi S. Successful Design, Conduct and Analysis of Clinical Trials in Oncology [(Invited) Plenary Presentation the 4<sup>th</sup> Interactive Genitourinary Cancer Conference, Advances in Prostate Cancer: Integrating New Strategies in Clinical Practice, Prague, March 2012].

Halabi S. Prostate-Specific Antigen Decline as a Surrogate for Overall Survival in Patients with Metastatic Castrate-Resistant Prostate Cancer Who Failed First-Line Chemotherapy. [Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2012].

Halabi S. Results of COU-302: Paradigm Shift? [(Invited Discussant) Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, June 2012].

Halabi S. Current Issues and Trends in Prognostic Models of Overall Survival in Men with Metastatic Castration Resistant Prostate Cancer. [(Invited) Presented at GU, Dana-Farber Cancer Institute, Boston, MA, November 2012].

Halabi S. Adjusting for Misclassification in Stratified Biomarker Trials [(Invited) Presented at the Johns Hopkins University, Baltimore, MD, February 2013].

Halabi S. A validated prognostic model for predicting overall survival in patients with metastatic chemotherapy naïve castrate-resistant prostate cancer [Presented at the European Society of Medical Oncology Annual Meeting, Amsterdam, September 2013].

Halabi S. Poster discussion for Abstracts 2863 (Ryan), 2864 (Scher), 2865 (Templeton). [(Invited Discussant) Presented at the European Society of Medical Oncology Annual Meeting, Amsterdam, September 2013].

Halabi S. Enrichment Trials: Worth their Weight? [(Invited) Presented at the Statistical Symposium Alliance Spring Meeting, Chicago, IL, November 2013].

Halabi S. Stratified Biomarker Design in the Presence of Classification Errors. [(Invited) Presented at the Society of Clinical Trials Annual Meeting, Philadelphia, PA, May 2014].

Halabi S. The Use of Penalized Regression Methods to Identify Subgroups [(Invited) Presented at the Society of Clinical Trials Annual Meeting, Philadelphia, PA, May 2014].

Halabi S. The Site of Visceral Metastases Predicts Overall Survival in Castration-Resistant Prostate Cancer Patients: A Meta-Analysis of 5 Phase III trials [Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2014].

Halabi S. Adjusting for Misclassification in the Design and Analysis of Stratified Biomarker Clinical Trials. [Presented at the Joint Statistical Meetings, Boston, MA, August 2014].

Halabi S. Interpreting Clinical Trials: New concepts, old pitfalls [(Invited) Presented at the St Gallen Advanced Prostate Cancer Consensus Conference (APCCC) St. Gallen, Switzerland, March 2015].

Halabi S. Smarter Trials: Revolution or Evolution? [(Invited Discussant) Presented at the 36th Annual Meeting for the Society of Clinical Trials, Arlington, VA, May 2015].

Halabi S. Data Monitoring Committees: Reflections and Controversies [(Invited) Presented at the AACR Workshop Methods in Cancer Biostatistics: Clinical Trial Designs for Targeted Agent, Lake Tahoe, CA, June 2015]

Halabi S. A Novel Test to Compare Two Treatments Based on Endpoints Involving Both Nonfatal and Fatal Events. [Presented at the ISBS/IDA Joint Symposium on Biopharmaceutical Statistics, Beijing, China, June 2015]

Halabi S. Data Monitoring Committees: Uses and Abuses [(Invited) Presented at the Duke Industry Statistics Symposium, Durham, NC, October 2015]

Halabi S. On the Design of a Stratified Biomarker Trial in the Presence of Measurement Error. Department of Biostatistics [(Invited) University of Pennsylvania, Philadelphia, PA, April 2016].

Halabi S. Challenges in the Design and Implementation of Oncology Trials with Immunotherapy [(Invited) Presented at the Duke Industry Statistics Symposium, Durham, NC, September 2016].

Halabi S. Lumpers or Slicers [(Invited) Presented at the second St Gallen Advanced Prostate Cancer Consensus Conference (APCCC) St. Gallen, Switzerland, March 2017].

Halabi S. Score Residuals In Survival Analysis With Full Likelihood Approach Using Proportional Hazards Model. [Presented at the ENAR Meeting in Washington DC, March 2017].

Halabi S. Innovative Designs for Early-Phase Clinical Trials [(Invited) Presented at the Centre for Quantitative Medicine, Duke-NUS Medical School, Singapore, March 2017].

Halabi S. On the Design of a Stratified Biomarker Trial in the Presence of Measurement Error [(Invited) Presented at the Quantitative Medicine Forum, Duke-NUS Medical School, Singapore, March 2017].

Halabi S. ASCO discussant for abstracts 5006-5008 [(Invited) the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2017].

Halabi S. Real World Experiences in Futility Analysis. [(Invited) Cens-ISBS, Vienna, Austria, August 2017].

Halabi, S. SWOG-Latin America Clinical Trials Course, Mexico City, Mexico, November 2017.

Halabi, S. Challenges in the Analysis of Immunotherapy Trials with Non-Proportional Hazards Duke-FDA Workshop: Duke Margolis Institute of Public Policy, Washington, D.C, March 2018.

Halabi S. Estimating and Interpreting Treatment Effect in Oncology Trials with Immune Therapies [(Invited). IISA, Gainesville, FL May 2018].

Halabi, S. Monitoring Complicated Trials in Oncology. Annual Meeting Society of Clinical Trials, Portland, OR May 2018.

Halabi S. Overall Survival Between African-American and Caucasian Men with Metastatic Castration-Resistant Prostate Cancer [Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2018].

Halabi S. Navigating Complicating Trials During Interim Analysis [(Invited) Presented at the Joint Statistical Meetings, Vancouver, British Columbia, Canada, August 2018].

Halabi S. Adjusting for misclassification in Stratified Biomarker Trials. [(Invited) Presented at the Department of Biostatistics, University of Michigan, October 2018].

Halabi S. The Promise and Power of Integrating Biomarkers into Clinical Trials [(Invited) Presented at the Department of Radiation Oncology, University of Michigan, October 2018].

Halabi S. Clinical Trials at NCI NCTN and beyond [(Invited) Presented at the AACR Cancer Health Disparities Think Tank, Washington, DC, October 2018].

Halabi S. Clinical Outcomes Between African-American and Caucasian Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC) [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Carlsbad, CA, October 2018].

Halabi S. Design of stratified biomarker trials with measurement error [(Invited) Presented at the Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute, November 2018].

Halabi S. New Directions in Predictive Modeling for Personalized Medicine (Invited) presented at the Department of Biostatistics and Epidemiology, School of Public Health, George Washington University, March 2019.

Halabi S. Design of stratified biomarker trials with measurement error (Invited) Presented at the Department of Biostatistics and Computational Biology, MD Anderson Cancer Center, Houston TX, April 2019.

Halabi S. Challenges in the Design of Immunotherapy Trials with Non-Proportional Hazards (Invited). Presented at the Society of Clinical Trials Annual Meeting, New Orleans, LA May 2019.

Halabi S. 3rd Pacific Rim Cancer Biostatistics Conference. Portland, OR, June 2019.

Halabi S. Subgroup Analysis of mCRPC Trials. Basel Switzerland, August 2019.

Halabi S. Part of a Panel Discussion Health Disparities [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Carlsbad, CA, October 2019].

Halabi S. Opportunities and Challenges in the Design and Implementation of Biomarker Driven Trials. iBright Conference, MD Anderson Cancer Center Houston, TX November 2019.

Halabi S. Clinical Trials Endpoints (Invited) Presented at the NCI Small Renal Masses Meeting, January 25, 2020.

Halabi, S. The Promise of Integrating Biomarkers into Modern Oncology Clinical Trials (Invited). Presented at the Department of Biostatistics, School of Public Health and Tropical Medicine, New Orleans February 2020.

### **Consultant Appointments:**

1995        Scientific Reviewer, United States Medical Research and Material Command, Scientific Peer Review for the Intramural Defense Women's Health Research Program

1996        Scientific Reviewer, United States Medical Research and Material Command, Scientific Peer Review for the Extramural Defense Women's Health Research Program

1996        Scientific Reviewer, United States Medical Research and Material Command, Scientific Peer Review for the Osteoporosis Research Program

1998        Scientific Reviewer, Epidemiology and Disease Control-2 Study Section National Institutes of Health

1998        Scientific Reviewer, Research Centers in Minority Institutions, Review Committee, National Institutes of Health

1998	Scientific Reviewer, Epidemiology and Disease Control-2 Study Section National Institutes of Health
1999	Statistical Consultant, Parke-Davis
1999	Participant in the NCI PSA consensus group
2000	Chair, Common Data Elements Committee for Bladder Cancer, National Cancer Institute
2001-2002	Member, Clinical Trial Design in the State of Rising PSA Workshop
2001	Scientific Reviewer, Epidemiology and Disease Control-2 Study Section National Institutes of Health
2001	Scientific Reviewer, Research Centers in Minority Institutions, Review Committee, National Institutes of Health
2002	Scientific Reviewer of SPORE applications in Prostate Cancer, National Institues of Health
2003	Scientific Reviewer, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health
2003-2006	Member of Compare Registry Steering Committee, Sanofi-Aventis
2003-2007	Member, Central Institutional Review Board, National Cancer Institute
2003-2007	Member, Cancer Biomarker Study Section, National Cancer Institute, National Institues of Health
2005	Participant, Clinical Trials Endpoints for Castration-Resistant/Hormone Refractory Prostate Cancer II
2005-2007	Member, ASCO Multiple Myeloma Special Panel
2005-2007	Statistical Consultant, GPC-Biotech
2005	Member, Prostate Program for the Assessment of Clinical Cancer Tests Working Group, NCI
2005-present	Member, DOD Prostate Cancer Consortium External Advisory Board, Memorial Sloan Kettering Cancer Center

2006-2009 Member, Data Monitoring Committee, OncoGenex Technologies

2006-2009 Member, Data Monitoring Committee, Texas Heart Institute

2007-present Member, External Advisory Committee, Research Center for Minority Institutions, Meharry College of Medicine, Nashville, TN

2007-2009 Member, Data Monitoring Committee (TROPIC Trial), Sanofi

2007-2009 Member, Cougar Biotech Scientific Advisory Committee

2007-2015 Special Government Employee, General and Plastic Surgery Devices Panel, Food and Drug Administration

2007-2011 *Ad-hoc* reviewer, Subcommittee H, NCI

2008-present Genitourinary (GU) Steering Coommittee, NCI

2009-2013 American Joint Committee on Cancer Modeler Working Group

2009-present Reviewer, Standing Peer Review Panel, Prostate Cancer Foundation

2010- Member, Data Monitoring Committee, PROSTVAC, BNIT

2010- Member, Data Monitoring Committee, Affinity Trial, Oncogenex

2010-2014 Member, Data Monitoring Committee, SYNERGY Trial, Oncogenex

2011- Chair, Data Monitoring Committee, FirstAna Trial, Sanofi

2011- Chair, Data Monitoring Committee, Proselica Trial, Sanofi

2013 *Ad-hoc* reviewer, Epidemiology of Cancer (EPIC) Study Section, NIH

2013-present Independent Statistician, Intermediate Clinical Endpoints in Cancer of the Prostate (ICECaP) Working Group

2013-2014 Reviewer, Special Emphasis Panel (SEP), NCI

2014 Scientific Reviewer, Prostate Cancer Review Panel, Population Science Impact Award, Department of Defense

2014-present American Joint Committee on Cancer, Precision Medicine Core Committee



- 2014-2015 Member of the Scientific Committee: Advanced Prostate Cancer Consensus Conference (APCCC 2015) St. Gallen, Switzerland
- 2015-2016 Member, Data Monitoring Committee, ARMOR3-SV PRONOUNCE Trial, Tokai
- 2015-present Member, Data Monitoring Committee, PRONOUNCE Trial, Ferring
- 2015-present *Ad-hoc* reviewer, Cancer Center Support Grants, NCI
- 2015-present Statistician, TAPUR Registry, American Society of Clinical Oncology
- 2016- *Ad-hoc* reviewer, Clinical Oncology Panel (ONCA), VA
- 2016-2017 Member of the Scientific Committee: Advanced Prostate Cancer Consensus Conference (APCCC 2017) St. Gallen, Switzerland
- 2016-2017 Reviewer, General and Plastic Surgery Devices Panel, Food and Drug Administration
- 2016-present Member, Data Monitoring Committee, E7080-307 Trial, Eisai
- 2017-present Member, Oncology Drugs Advisory Committee (ODAC), Food and Drug Administration
- 2018-2019 Member of the Scientific Committee: Advanced Prostate Cancer Consensus Conference (APCCC 2019) Basel, Switzerland

**Organizations and Participation:**

- 1996-2000 ENAR Correspondent, Biometric Bulletin, International Biometric Society
- 2002-2004 Member of the Regional Advisory Board, ENAR, International Biometric Society
- 2003-2005 Representative, Council of Section, Biometrics Section, American Statistical Association
- 2004 Member, ENAR Spring Meeting Program Committee
- 2004-2005 Member and Chair (2004) of Biostatistics Track Committee, Scientific Program Committee, American Society of Clinical Oncology
- 2005 Students Awards Committee, ENAR Spring Meeting Program
- 2006-2008 Member, Committee on Career Development, American Statistical Association
- 2007-2011 Program Committee, Society of Clinical Trials

- 2007-2011 Education Committee, Society of Clinical Trials
- 2008-2011 Member, Grant Selection Committee, American Society of Clinical Oncology
- 2009-2011 Membership Committee, Society of Clinical Trials
- 2012-2014 Member, Board of Directors, Society of Clinical Trials
- 2012-2014 Member (2012) and Chair of Biostatistics Track (2013), Scientific Program Committee, American Society of Clinical Oncology
- 2015-2017 Member of the Regional Advisory Board, ENAR, International Biometric Society
- 2015-2016 Nomination Committee, Society of Clinical Trials
- 2016-present Member, TAPUR Steering Committee, American Society of Clinical Oncology
- 2016-present Fellows Committee, Chair, Society of Clinical Trials
- 2016-2019 Member of Biostatistics Track Committee, Scientific Program Committee, American Society of Clinical Oncology
- 2018- Member, Southwest Oncology Group (SWOG) NCORP External Advisory Committee
- 2018- American Statistical Association, COPSS Presidents' Award Committee (Chair, 2020)
- 2018-2019 Member, Updating Labels for Generic Oncology Drug, National Academies of Sciences, Engineering, and Medicine
- 2019-2020 President Elect, Society of Clinical Trials
- 2020 Member, Executive Committee, Society of Clinical Trials

**Participation in academic and administrative activities of the University and Medical Center: [at Duke only]**

- 1996-2001 Biostatistics Core Director, Improving Cancer Risk Communication
- 2000 Cancer Protocol Committee, Duke University Comprehensive Cancer Center
- 2000-2001 Member, Search Committee, Cancer Center Biostatistics

- 2003-2004 Member, Scientific Committee, Critical Assessment of Microarray Data Analysis Conference, Duke University Medical Center
- 2005-2006 Member, Education and Training Committee, Department of Biostatistics and Bioinformatics
- 2005-2006 Member, Curriculum Subcommittee, Education and Training Committee, Department of Biostatistics and Bioinformatics
- 2005-2006 Chair, Mission Subcommittee, Education and Training Committee, Department of Biostatistics and Bioinformatics
- 2005- Member, Cancer Prevention and Control, Duke University Comprehensive Cancer Center
- 2005- Member, Appointments, Promotion and Tenure Committee, Department of Biostatistics and Bioinformatics
- 2006-present Biostatistics Core, DOD Prostate Cancer Clinical Trials Consortium
- 2006-2008 Member, Clinical Sciences Faculty Council on Academic Affairs, Duke University Medical Center
- 2006-2008 Member, Basic Science Faculty Steering Committee, Duke University Medical Center
- 2008-2011 Member, Search Committee, Department of Biostatistics and Bioinformatics, Duke University Medical Center
- 2010-2011 Member, Search Committee, Cancer Control, Duke University Medical Center
- 2012- Member, Professional Advisory Council, Department of Biostatistics and Bioinformatics, Duke University Medical Center
- 2018- Member, Doctoral Students Qualifying Exams, Department of Biostatistics and Bioinformatics, Duke University Medical Center
- 2018- Member, Doctoral Students Admissions Committee, Department of Biostatistics and Bioinformatics, Duke University Medical Center

**Teaching responsibilities, including continuing education:**

- 1994-1996 Introduction to Biostatistics, Categorical Data Analysis, Introduction to Medical Statistics, Tulane University School of Public Health and

Tropical Medicine, and School of Medicine, New Orleans, LA

1999 Intuitive Biostatistics, Duke University Medical School, Duke University, Durham, NC

2002 Statistical Considerations in Clinical Trials in Oncology, The Henry Ford Systems, Detroit, MI

2003 Group Sequential Monitoring in Clinical Trials. Graduate course offered at Tulane University School of Public Health, New Orleans, LA

2005-06 Duke University/FDA Workshop "Accelerating Anticancer Agent Development and Validation." Bethesda, MD

2005-12 Course Co-Director (CRP248), Clinical Trials, Clinical Research Training Program, Duke University School of Medicine

May 2011 Workshop co-Director: Essentials of Randomized Clinical Trials, 32 Annual Meeting, Society of Clinical Trials Vancouver, British Columbia, Canada

May 2012 Workshop co-Director, Essentials of Randomized Clinical Trials, 33 Annual Meeting, Society of Clinical Trials, Miami, FL.

May 2012 Course Director, Designs for Contemporary Early-Phase Clinical Trials, American Society of Clinical Oncology  
June 2012

Fall 2013- Course Director, Clinical Trials, Clinical Research Training Program, Duke University School of Medicine  
Present

June 2015 Faculty Member, American Association for Clinical Research Workshop Methods in Cancer Biostatistics: Clinical Trial Designs for Targeted Agent, Lake Tahoe, CA

11/ 2015 Faculty, Statistical Course, Latin America Cooperative Oncology Group, Mexico City, Mexico.

3/2016 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Mexico City, Mexico.

11/2016 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Bogota, Colombia

11/2017 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Mexico City, Mexico

11/2018 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Bogota, Colombia

2019- Course Co-Director, Statistical Analysis (CRP245), Clinical Research Training Program,  
Duke University School of Medicine

### **Editorial Activities**

1/08-12/14 *Journal of Clinical Oncology* Editorial Board  
11/11-present Associate Editor, *Clinical Trials*  
1/14-present Statistical Advisor Consulting, *Nature Publishing Group*  
1/15-present *Annals of Oncology* Editorial Board  
2016-present Associate Editor, *Diagnostic and Prognostic Research*  
2017-present Associate Editor, *Statistics in Medicine*

### **Journal Peer Reviewer Activities**

Statistics in Medicine, Biometrics, Biometrika, Biometrical Journal, Communication in Statistics, Clinical Trials, Biostatistics, Statistical Methods in Medical Research, Nature, Journal of the National Cancer Institute, Lancet Oncology, Journal of Clinical Oncology, Cancer Research, Clinical Cancer Research, Cancer, Annals of Oncology, Urology, Journal of Urology, British Journal of Urology, European Journal of Urology.

### **Students Advised**

Amparo Gordillo -MPH in Epidemiology, School of Public Health, Tulane University, 1995-1996.  
Lisa Cunningham- MS in Biostatistics, School of Public Health, Tulane University, 1995-1996.

### **Served on Thesis Committee**

Nicole McCarthy, M.D., CRTP, Duke University Medical Center, 2002  
Vidya Sankar, M.D., CRTP, Duke University Medical Center, 2003  
Joseph Kay, CRTP, M.D., Duke University Medical Center, 2004  
Ed Cowen, CRTP, M.D., Duke University Medical Center, 2006  
Habib Ramadhani, M.D., CRTP, Duke University Medical Center, 2008  
Mark W. Onaitis, M.D., CRTP, Duke University Medical Center, 2009  
Anna Teeter, M.D., CRTP, Duke University Medical Center, 2010-  
Mazen Nouredin, M.D., CRTP, NIH, 2011-2017  
Laleh Amiri-Kordestani, M.D., CRTP, NIH 2012-  
Nan Soon Wang, M.D., CRTP, CRTP, 2012-2015  
Nicole Solomon (Chair), MS in Biostatistics, Duke University, 2012-2013  
Rui Zou, MS in Biostatistics, Duke University, 2012-2013  
Siyun Yang (Chair), MS in Biostatistics, Duke University, 2014-2015  
Stephanie (Xizi) Sun, MS in Biostatistics, Duke University, 2015-2016  
Yao Song, MS in Biostatistics, Duke University, 2016-2017  
Lina Yang, MS in Biostatistics, Duke University, 2016-2017  
Paul L. Feingold, M.D. CRTP, NIH, 2016-2018

Mengdi Xuan (Chair), MS in Biostatistics, Duke University, 2018-2019  
Bohui Zhang (Chair), MS in Biostatistics, Duke University, 2018-2019  
Chenyang Wang, MS in Biostatistics, Duke University, 2019-  
Siqi Zhang, MS in Biostatistics, Duke University, 2019-  
Kenny Zhang (Chair), MS in Biostatistics, Duke University, 2019-  
Andrea McCormack (Chair), MS in Biostatistics, Duke University, 2019-  
Gongbo Xie, MS in Biostatistics, B&B, Duke University, 2019-present  
Oliver Jawitch, MD, CRTP, NIH, 2019-current

Lu Liu, PhD Student, rotation, Fall 2019  
Zidi Xiu, PhD Student, rotation, Spring 2019

#### **Doctoral Dissertation Committee**

Sangmi Kim, Department of Epidemiology, University of North Carolina, Chapel Hill, NC, 2006-07.  
Tongrong Wang, Ph.D. in Biostatistics, Duke University, 2018-

#### **Post-doctoral Fellows**

Tong Shen, Ph.D., 2011-2012  
Chen-Yen Lin, Ph.D., 2012-2013  
Ivo Shterev, Ph.D., 2012-2013  
Haojin Zhou, Ph.D., 2013-2014  
Greg-Mayhew, Ph.D., 2013-2014  
Zhenyu Wang, Ph.D., 2014-2015  
Hua Ma, Ph.D., 2014-2016  
Anna-Maria Masci, Ph.D., 2015-present  
Lira Pi, Ph.D., 2015-2018  
Sangjin Kim, Ph.D., 2015-2017  
Sandipan Dutta, Ph.D., 2016-2019  
Duy Thai, Ph.D., 2018  
Qian Yang, Ph.D., 2020-present

#### **Areas of Research Interest**

Data Science  
Prognostic and Predictive Models  
Biomarkers  
Personalized Medicine  
Clinical Trial Methodology  
Surrogate Endpoints  
High dimensional data  
Meta-Analysis  
Health disparity