Curriculum Vitae for: Michael J. Schell, Ph.D. Date: November 16, 2018

Current Position: Senior Member, Biostatistics and Bioinformatics Department Chair of the Appointment, Promotion & Tenure Committee H. Lee Moffitt Cancer Center & Research Institute 12902 Magnolia Drive, MRC-Bio2 Tampa, FL 33612-9416 (813) 745-6061 (813) 745-6107 (fax) Michael.Schell@moffitt.org

Current Academic Appointments

Professor Department of Oncologic Sciences College of Medicine University of South Florida 12901 Bruce B. Downs Blvd. Tampa, FL 33612

Education

1981 - 1984	Ph.D. Statistics, Florida State University, Tallahassee, FL
1979 - 1981	M.S. Statistics, Florida State University, Tallahassee, FL
1975 - 1979	B.S. Mathematics, University of North Carolina, Charlotte, NC
1975 - 1979	B.A. Sociology, University of North Carolina, Charlotte, NC

Academic Appointments and Employment

2014-Present	Senior Member, Biostatistics and Bioinformatics Department, Moffitt Cancer Center, Tampa, Florida
2013-2014	Senior Member and Interim Chair, Biostatistics and Biomedical Informatics Department, Moffitt Cancer Center, Tampa, Florida
2008-2013	Senior Member and Biostatistics Department Chair, Moffitt Cancer Center, Tampa, Florida
2008-Present	Professor , Department of Oncologic Sciences, College of Medicine, University of South Florida, Tampa, Florida
2006-Present	Adjunct Professor, Department of Epidemiology and Biostatistics, University of South Florida, Tampa, Florida
2005-Present	Scientific Director, Biostatistics Shared Resources, Moffitt Cancer Center, Tampa, Florida
2005-2007	Professor and Biostatistics Division Chief , Department of Interdisciplinary Oncology, Moffitt Research Center, Tampa, Florida
2003-2005	Research Professor , Department of Biostatistics, University of North Carolina, Chapel Hill, North Carolina
1995-2005	Director of Biostatistics Shared Resource , Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, North Carolina
1991-2003	Research Associate Professor, Department of Biostatistics, University of

North Carolina, Chapel Hill, North Carolina

- 1994-1995 **Director of Biostatistics Shared Resource**, Chao Family Clinical Cancer, University of California, Irvine, California
- 1991-1995Associate Professor and Director of Biostatistics, University of California,
Irvine, California
- 1990-1991 **Associate Member**, Division of Biostatistics and Information Systems, St. Jude Children's Research Hospital, Memphis, Tennessee
- 1989-1991Adjunct Assistant Professor, University of Tennessee, Memphis,
Tennessee
- 1984-1990 Assistant Member, Division of Biostatistics, St. Jude Children's Research Hospital, Memphis, Tennessee

Teaching Experience

Other Courses and National Symposia

Short Courses/Lectures

March 2018	"Design and Conduct of Clinical Trials", Translational Biology Course (GMS 6069), USF, 2 hour lecture.
Spring 2018	BIOS 101 for Moffitt Employees. "Laboratories and Experiments Basics" and Introduction to Clinical Trials", (Two, 1-hour lecture), Moffitt Cancer Center.
Spring 2017	BIOS 101 for Moffitt Employees. "Laboratories and Experiments Basics", (1-hour lecture), Moffitt Cancer Center.
April 2017	"Statistical Testing" and "Keeping Up with Statistical Practice", Biostatistics Case Studies and Collaborations I, 3-hour class.
March 2017	"Design and Conduct of Clinical Trials", Translational Biology Course (GMS 6069), USF, 2 hour lecture.
November 201	6 "Strategies for Effective Clinical Trial Design and Biostatistics Resources", Clinical Research Lecture Series (1-hour lecture).
June 2016	"Colorectal Cancer Mutation Landscape", SPECS II Conference, Albuquerque, NM, June 29-July 1.
April 2016	"Statistical Testing" and "Keeping Up with Statistical Practice", Biostatistics Case Studies and Collaborations I, 3-hour class.
March 2016	"Design and Conduct of Clinical Trials", Translational Biology Course (GMS 6069), USF, 2 hour lecture.
Fall 2015	BIOS 101 for Moffitt Employees. "Laboratories and Experiments Basics" and "Introduction to Clinical Trials", (Two, 1-hour lectures), Moffitt Cancer Center.

- April 2015 "Statistical Testing" and "Keeping Up with Statistical Practice", Biostatistics Case Studies and Collaborations I, 3-hour class.
- March 2015 Translation Biotechnolgy lecture on clinical trials and survival analysis, USF, (2 hours)
- Spring 2015 Bioinformatics 101, "Next-generation sequencing", (1 hour co-lecture)
- Fall 2014BIOS 101 for Moffitt Employees. "Laboratories and Experiments Basics" and
"Introduction to Clinical Trials", (Two, 1-hour lectures), Moffitt Cancer Center.
- June 2014 "Classifying Colorectal Cancers Using Targeted Exome Sequencing", SPECS II Meeting, Boston, MA.
- June 2014 "Statistical Testing" and "Keeping Up with Statistical Practice", Biostatistics Case Studies and Collaborations I, 3-hour class.
- April 2014 "Introduction to Biostatistics Resources", Clinical Research Lecture Series, Moffitt Cancer Center.
- October 2013 "Classifying Colorectal Cancers Using Targeted Exome Sequencing", Biostatistics Journal Club, Moffitt Cancer Center
- August 2013 "Introduction to Next Gen Sequencing
- June 2013 Direction of Summer Project of 2 undergraduate students for the NHLBI-funded Summer Institute for Training in Biostatistics (SIBS) summer experience in conjunction with Dr. Yiliang Zhu in the department of Epidemiology and Biostatistics at the University of South Florida.
- Spring 2013 BIOS 101 for Moffitt Employees. "Introduction to Biostatistics" and "Clinical Trials", (Two, 1-hour lectures), Moffitt Cancer Center.
- Spring 2013 "Statistical Testing" and "Keeping Up with Statistical Practice", Biostatistics Case Studies and Collaborations I, 3-hour class.
- June 2012 Partial Direction of Summer Projects of 9 undergraduate students (3 teams of 3 each) for the NHLBI-funded Summer Institute for Training in Biostatistics (SIBS) summer experience in conjunction with Dr. Yiliang Zhu in the Department of Epidemiology and Biostatistics at the University of South Florida (managed 3-4 30-minute visits per team over a 5-week period)
- Spring 2012 "Statistical Test Decision Making." School of Public Heath, University of South Florida "Biostatistical Case Studies and Collaboration I" 3 hour class.
- Fall 2011BIOS 101 for Moffitt Employees, "Introduction to Biostatistics" and "Statistical
Testing I" Moffitt Cancer Center.

Spring 2011	"Statistical Test Decision Making." School of Public Heath, University of South Florida "Biostatistical Case Studies and Collaboration I" 3 hour class.	
June 2011	Partial Direction of Summer Projects of 9 undergraduate students (3 teams of 3 each) for the NHLBI-funded Summer Institute for Training in Biostatistics (SIBS) summer experience in conjunction with Dr. Yiliang Zhu in the Department of Epidemiology and Biostatistics at the University of South Florida (managed 3-4 30-minute visits per team over a 5-week period)	
Spring 2011	Statistical Test Decision Making." School of Public Heath, University of South Florida "Biostatistical Case Studies and Collaboration I" 3 hour class.	
June 2010	Direction of Summer Projects of 10 undergraduate students (2teams of 5each) for the NHLBI-funded Summer Institute for Training in Biostatistics (SIBS) summer experience in conjunction with Dr. Yiliang Zhu in the department of Epidemiology and Biostatistics at the University of South Florida (managed 12 3-hour visits per team over a 6-week period)	
Spring 2010	"Statistical Test Decision Making." School of Public Heath, University of South Florida "Biostatistical Case Studies and Collaboration I" 3 hour class.	
Spring 2009	"Statistical Test Decision Making." School of Public Heath, University of South Florida "Biostatistical Case Studies and Collaboration I" 3 hour class.	
Spring, 2009	BIOS 101 for Moffitt Employees, "Introduction to Biostatistics" and "Statistical Testing I" Moffitt Cancer Center.	
Fall 2008	BIOS 101 for Moffitt Fellows, "Introduction to Biostatistics" and "Statistical Testing I" Moffitt Cancer Center.	
Fall 2008	"Statistical Testing Issues." Moffitt Cancer Biology Ph.D. Graduate Program (one lecture).	
Spring 2008	"Introduction to Biostatistics" Ponce School of Medicine, Puerto Rico	
Fall 2007	"Statistical Testing Issues." Moffitt Cancer Biology Ph.D. Graduate Program (one lecture).	
Fall 2004	"Statistical Issues in Clinical Trials" for Hematology/Oncology Fellow (2 sessions).	
Fall 2000/ Fall 2002	"Statistics for Radiation/Oncology Fellows," (4 sessions), University of North Carolina.	
May 1995	"Clinical Trials: Statistical Issues in Planning and Management," one-day course, University of California Extension Course.	
May 1994	"Statistics for Scientific Researchers" one-day course, University of California Extension Course.	

Fall 1994	"Statistics for Radiation/Oncology Fellows" (3 of 8 session course), University of California, Irvine.
Fall 1992	"Statistics for Radiation/Oncology Fellows" (3 of 8 session course), University of California, Irvine.
Spring 1989	"Introduction to Biostatistics" (4 of 16 session course), St. Jude Children's Research Hospital, Memphis, Tennessee.

Teaching and Training Experience:

Undergraduate training:

SPGRE Advisor (Special Program of Graduate Excellence, a summer internship program for the undergraduate minorities.)

2003	Roderick Brannan, Choosing the Best Test for the Two-Single Location Problem for Small Samples.
1998	Brandy Rutledge, A Statistical Analysis of How the Types of p53 mutations found in the Carolina Breast Cancer Study compared to those from other studies.
1998	Carin Lightner, An Exploration of Phylogenetic Trees in the GAG Gene of HIV-1 Nucleotide Sequences.
1997	Brandy Rutledge, and Carin Lightner, A Statistical Analysis of Amino Acid and Codon Usage in Organisms.

Graduate training:

Master Thesis Advisor

2003	Binbin Zhang, Two-Sample Location Problem with Small Samples: Power Comparison of Parametric and Non-Parametric Tests, UNC-Chapel Hill, Biostatistics.
2002	Fang Gai, James-Stein Estimation, UNC-Chapel Hill, Biostatistics.
2001	Daniel Scharf, Matrix Order Reduced Isotonic and Reduced Monotonic Regression, UNC-Chapel Hill, Biostatistics, 2001. (Won award as one of Best Master's Papers of 2001.)
2000	Trang Lance, Early Analytic Evaluation of Practice and Radiologist Variation in the Density Assessment of Screening Mammograms, UNC-Chapel Hill, Biostatistics.
1997	Shibing Deng, Computation and Studies on Maximally Selected Chi-Square Statistics, Biostatistics, UNC-Chapel Hill, 1997. (Won award as Best Master's Paper of 1997.)
1997	Sean O'Brien, Optimal Grouping Strategies for Categorizing Continuous Explanatory Variables, UNC-Chapel Hill, Biostatistics.
1997	Stefanie Silva, Comparison of Ischemic Pain Intensity Ratings on TMD and Control Populations: A Mixed Model Analysis of Longitudinal Data, UNC- Chapel Hill, Biostatistics.

Master Thesis Committee

2001	Ahinee Amamoo, UNC-Chapel Hill, Biostatistics
1997	Pamela Sue LaDuke, UNC-Chapel Hill, Biostatistics
1995	Craig Uejo, San Diego State University, Public Health

Doctoral Field Experience

2014-15	Muditha Perera,	Dent	of Mathema	ntics and	Statistics	USF
2014-15	windina i cicia,	Dept.		uics and	statistics,	USI

Master Field Experience

2015	Mentor for Ms. Mahrukh Naqvi, Dept. of Epidemiology and Biostatistics, USF
2010	Mentor for Mr. Yong Xu, Graduate Teaching Assistant, Dept. of Statistics, USF
2010	Mentor for Mr. Zhengming Chen, Dept. of Epidemiology and Biostatistics, USF
2006	Mentor for Mr. Xiaowu Zhou, Dept. of Epidemiology and Biostatistics, USF

Doctoral Committee

2003	Kai Wang, UNC-Chapel Hill, Biostatistics
2003	Ji-Hyun Lee, UNC-Chapel Hill, Biostatistics
2003	Lynette Phillips, UNC-Chapel Hill, Epidemiology
2003	Brian Neelon, UNC-Chapel Hill, Biostatistics
2002	Sean O'Brien, UNC-Chapel Hill, Biostatistics
2000	Michael Cassell, UNC-Chapel Hill, Health Behavior Health Education
2000	Joe Galanko, UNC-Chapel Hill, Biostatistics
2000	Lynne Wilkens, UNC-Chapel Hill, Biostatistics
1999	Eric Duell, UNC-Chapel Hill, Epidemiology
1998	Wen-Yi Huang, UNC-Chapel Hill, Epidemiology
1998	Susan Hastings, UNC-Chapel Hill, Nutrition
1998	Dina Schreinemachers, UNC-Chapel Hill, Biostatistics
1997	Zuzana Bic, Loma Linda University, Preventive Care & Epidemiology

Graduate Research Assistanceships

2004-2005	Laura Lapkauskaite
2003 - 2005	Jaeun Choi
2003 - 2005	Yeonseong Chung
2002	Yanfang Zhiang (Information Science)
2001 - 2003	Liyun Ni
2000 - 2001	Yun Li
2000 - 2003	Ji-Hyun Lee
2000 - 2003	Jackie Johnson
1998 - 2000	Shen Zhuang
1998 - 2000	Ahinee Amamoo

1997 – 2003 Brian Nelson

 1996
 Shibing Deng

 1995 - 2002
 Sean O'Brien

Full-Time Staff Statisticians Under Supervision

Moffitt Cancer Center and Research Institute, University of South Florida

- 2016 Present Junmin Zhou
- 2016 2017 Braydon Schaible
- 2015 Present Jiannong Li
- 2015 Present Mahrukh Naqvi
- 2015 Present Ram Thapa
- 2015 2016 Nelson Torres
- 2014 2015 Tzu-Hua Juan
- 2011 2015 Binglin Yue
- 2011 2015 Kate Fisher
- 2009 2011 Gang Han
- 2009 2010 Lulu Yan
- 2008 2011 Bhupendra Rawal
- 2008 2015 Xiuhua Zhao
- 2007 2015 Jimmy Fulp
- 2006 2007 Gui Gao
- 2005 2008 Rachna Kapoor
- 2005 2008 David Boulware

Lineberger Comprehensive Cancer Center, University of North Carolina

- 2004 2005 Li Lin
- 1999 2005 Dominic Moore
- 1997 1998 Ahinee Amamoo
- 1997 1998 Sean O'Brien
- 1996 2001 Yuhua Lin

Honors and Awards

B.S. and B.A. degrees earned magna cum laude

A.K. Anderson award at the University of North Carolina, Charlotte, NC in 1979 (top graduating mathematics student)

Teaching Fellowship at Florida State University, Tallahassee, FL 1979-80

University Fellowship at Florida State University, Tallahassee, FL 1983-84

Delta Omega, Theta Chapter, 1999

Outstanding Faculty Performance Award, Population Science Division, Moffitt Cancer Center & Research Institute, 2014

Faculty Statistician of the Year, Biostatistics Core, 2017

Research Support

<u>Current</u>

External Grants

Account: Name of PI: Dates: Funding Source: Title: % Effort: Role in the study: Total Direct Costs: Total Amount of Award: Date Submitted:

Account: Name of PI: Dates: Funding Source: Title:

% Effort: Role in the study: Total Direct Costs: Total Amount of Award: Date Submitted:

Account: Name of PIs: Dates: Source: Title:

% Effort: Role in the Study: Total Direct Costs: Total Amount of Award:

Account: Name of PI: Dates: Funding Source: Title:

% Effort: Role in the study: Total Direct Costs: Total Amount of Award:

(Heine)

04/01/2019 – 03/21/2022 State of Florida—Bankhead Coley Understanding breast structure with Deep Learning 3% Co-Investigator \$781,862 \$117,279 October 2018

(Shain/Silva)

07/25/2018 – 06/30/2020 Multiple Myeloma Research Foundation Big data and machine learning to inform care pathways on the use of maintenance therapy in multiple myeloma 10% Co-Investigator \$453,888 \$998,554 March 2018

(Giuliano)

\$4,277,635

08/01/2017 – 09/30/2018 Merck & Co., Inc. The Role of Genital Warts in HIV Acquisition among Men Participating in a Longitudinal Study from the United States, Brazil and Mexico 5% Co-Investigator \$319,808 \$415,750 5 R01 CA214588 (Giuliano) 04/01/2017 – 03/31/2022 NIH/NCI

Investigation of Oral HPV Infection Natural History and Biomarkers of Persistent Infection- The HIM Study 4% Co-Investigator \$2,492,625

1U48DP005024-01 Account: Nome of PI: (Baldwin/ Gwede) 09/30/2014 - 09/29/2019Dates: Source: CDC Title: Community Based Prevention Marketing for Systems Change: **Reducing Disparities** Effort: 2% Role in the Study: Co-Investigator/Biostatistician \$49,074 USF main= \$615,229 Total Direct Costs: \$73,366 USF Main = \$750,000 Total Amount of Award: Account: 5 R01 CA177586 Name of PI: (Rollison) 04/02/2014 - 02/28/2019Dates: Source: NIH/NCI Title: Prospective Study of Cutaneous Viral Infections and Non-Melanoma Skin Cancer % Effort: 6% Role in the Study: **Co-Investigator** \$1,994,194 Total Direct Costs: Total Amount of Award: \$3,354,636 Account: 5P30CA07692 Name of PI: (Sellers) 02/01/12 - 01/31/2022Dates: Source: NIH/NCI H. Lee Moffitt Cancer Center and Research Institute Support Title: Grant % Effort: 10% Role in the Study: **Biostatistics Core Principal Investigator** Total Direct Cost: \$7.825.195 Total Amount of Award: \$13,459,335 Account: 8JK03 (Kumar) Name of PI: 05/03/2018 - 03/31/2023Dates: Funding Source: State of Florida/ JEK Title: Chemoprevention of Lung Cancer in Former Smokers % Effort: 3% Role in the study: Co-Investigator Total Direct Costs: \$265,000 Total Amount of Award: \$1,325,000

Pending

External Grants

Account:

Name of PI: Dates: Funding Source: Title:

Role in the study:

Date Submitted:

Total Direct Costs:

Total Amount of Award:

% Effort:

(Vadaparampil/Christy)

04/01/2019 – 03/31/2024 State of Florida- JEK HPV PRACTICE: Promoting Rates of Acceptance and Completion with Technology, Intervention, Communication, and Education 5% Co-Investigator \$1,279,778 \$1,471,746 November 2

Account: Name of PI: Dates: Funding Source: Title:

% Effort: Role in the study: Total Direct Costs: Total Amount of Award: Date Submitted:

Account: Name of PI: Dates: Funding Source: Title: % Effort: Role in the study: Total Direct Costs: Total Amount of Award: Date Submitted:

Account: Name of PI: Dates: Funding Source: Title:

% Effort: Role in the study: Total Direct Costs: Total Amount of Award: Date Submitted:

Account:

(Meade/Gwede)

04/01/2019 – 03/31/2023 State of Florida- Bankhead Coley CARES-REACH (Colorectal Cancer Awareness, Research, Education and Screening-Rural Expansion, Access and Capacity for Health 5% Co-Investigator \$1,304,347 \$1,499,999 November 2018

(Kumar)

04/01/2019 – 03/31/2024 State of Florida- Bankhead Coley Phase II Clinical Trial of GTC in Men on Active Surveillance 10% Co-Investigator \$1,307,125 \$192,870 March 2018

(Kumar)

07/01/2019 – 06/30/2024 NIH/NCI Phase II Clinical Trial of Green Tea Catechin in Men on Active Surveillance 10% Co-Investigator \$2,350,435 \$3,883,016 November 2018

Name of PI: Dates: Funding Source: Title: % Effort: Role in the study: Total Direct Costs: Total Amount of Award:	(Heine) 07/01/2019 – 06/30/2023 NIH Understanding the Structure of Mammograms with Deep Learning 10% Co-Investigator \$ 1,825,302 \$ 3,134,849
Account: Name of PI: Dates: Funding Source: Title:	R01 CA227529-01 (Kumar) 04/01/2019 – 03/31/2024 NIH (PQ11) Phase II Clinical trial valuating the safety, effectiveness and mechanism by which a Ketogenic Diet reduces biomarkers od disease progression in patients diagnosed with low grade gliomas
% Effort:	10% (resubmission)
Role in the study:	Co-Investigator
Total Direct Costs:	\$ 2,306,717
Total Amount of Award:	\$ 3,792,782
Account:	(Kumar)
Name of PI:	04/01/2019 – 03/31/2023
Dates:	NIH
Funding Source:	A Randomized, Phase II Clinical Trial of Sulforaphane in
Title:	Bladder Cancer Chemoprevention
% Effort:	10%
Role in the study:	Co-Investigator
Total Direct Costs:	\$ 1,562,141
Total Amount of Award:	\$ 2,599,596
Account: Name of PI: Dates: Funding Source: Title: % Effort: Role in the study: Total Direct Costs: Total Amount of Award:	(Kumar) 01/01/2019 – 12/31/2023 NIH A phase II clinical trial of levothyroxine in ameliorating symptoms of fatighe and other symptoms cluster in Breast cancer survivors 10% Co-Investigator \$ 2,123,916 \$ 3,250,468
Account:	R01
Name of PI:	(Kumar)
Dates:	09/01/2018 – 08/31/2022
Funding Source:	NIH

Title:	Phase II Clinical Trial of GTC in Men on Active Surveillance
% Effort:	10%
Role in the study:	Co-Investigator
Total Direct Costs:	\$1,682,112
Total Amount of Award:	\$2,865,648
Date Submitted:	March 2018
<u>Completed</u> External Grants:	
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	5R01HL114994 (Anasetti) 08/01/13 – 04/30/18 NIH/NHLBI Adoptive Transfer of Donor Tregs Specific Against Host Alloantigens for Prevention of Human GVHD 5% Co-Investigator \$277,904 \$468,268
Account:	4P50CA168536
Name of PI:	(Sondak)
Dates:	09/20/13 – 07/31/18
Source:	NIH/NCI
Title:	Moffitt Skin Cancer SPORE
% Effort:	15%
Role in the Study:	Co-Director, Core B
Total Direct Costs:	\$6,641,749
Total Amount of Award:	\$10,149,665
Account:	02-60000-18-01
Name of PIs:	(Kumar)
Dates:	07/01/2017-06/30/2018
Source:	State of Florida/ MCC
Title:	Medical Marijuana Research and Education
% Effort:	7% effective 03/01/2018 through 06/30/2018
Role in the Study:	Biostatistician
Total Direct Costs:	\$648,968
Total Amount of Award:	\$746,313
Account: Name of PIs: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs:	54974 (Giuliano) 08/01/2017 – 02/28/2018 Merck & Co., Inc. Oral HPV Antibody Kinetics and Function Post-Vaccination among HIV- and HIV + Men 3% Co-Investigator \$198,805

Total Amount of Award:	\$150,000
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	4U01CA157960-05 (Yeatman; Schell, Moffitt PI) 09/19/12 – 08/31/17 NIH / NCI Individualizing Colon Cancer Therapy Using Hybrid RNA and DNA Molecular Signature 9% Co-Investigator \$1,915,278 \$2,560,539
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	5R01CA160104-05 (Craig) 09/09/11 – 07/31/16 (Effort completed 04/07/2016) NIH/NCI HRQoL Values For Cancer Survivors: Enhancing PROMIS Measures for CER 6% Biostatistician Co-Investigator \$2,091,804 \$3,129,188
Account:	Pending
Name of PI:	(Mulé)
Source:	Sullivan Fund
Dates:	11/21/2013 – 11/20/2016 (Effort completed 10/01/2015)
Title:	"Project 3 – Improving Patient Survival"
% Effort:	10%
Role:	Co-Investigator
Total Direct Costs:	\$1,400,001
Total Amount of Award:	\$1,400,001
Account:	5P50CA119997-05
Name of PI:	(Haura)
Dates:	09/15/08 – 08/31/14 (NCE status)
Source:	NIH
Title:	SPORE in Lung Cancer
% Effort:	15% years 1-4, 10% year 5, 5% during NCE
Role in the Study:	Statistical Co-investigator
Total Direct Cost:	\$6,099,694
Total Amount of Award:	\$10,000,000
Account:	5R01CA122060-05
Name of PI:	(Kumar)
Dates:	07/01/07 – 05/31/14
Source:	NIH/NCI
Title:	A Phase II Clinical trial of Polyphenon E in Prostrate Cancer
% Effort:	2.5% (Effort completed 01/2014)
Role in the Study:	Co-Investigator

Total Direct Costs: \$ 2,304,660.85 Total Amount of Award: \$ 3,544,690 9R01CA132197-06A2 Account: Name of PI: (Anasetti) 08/25/08 - 07/31/13 Dates: Source: NIH Antigen Specific T Cell Tolerance by Anti CD3 Antibodies Title: 5% % Effort: Statistical Co-investigator Role in the Study: Total Direct Costs: \$1,105,067 Total Amount of Award: \$1,843,468 Account: 1R01 CA131080-01A2 Name of PI: (Lengacher/Schell) 02/01/09 - 6/30/13 Dates: Source: USF Title: MBSR Symptom Cluster Trial for Breast Cancer Survivors % Effort: 2% Role in the Study: Statistical co-investigator Total Direct Costs: \$25,213 Total Amount of Award: \$223.295 1R01CA122060-01A1 Account: Name of PI: (Kumar) 07/01/08 - 05/31/13Dates: Source: NIH Phase II Clinical Trial of Polyphenon E in Prostate Cancer Title: % Effort: 5% (downshifted to 2.5% during extension) Role: Statistical co-investigator Total Direct Costs: \$569,244 Total Amount of Award: \$700,250 R01 CA129343 Account: Name of PI: (Bepler) 04/01/08 - 01/31/2013Dates: Source: NIH/NCI Title: RRM1 in the Management of Lung Cancer % Effort: 5% Role: Statistical co-investigator Total Direct Costs: \$379.321 Total Amount of Award: \$3,470,614 Account: 5R01CA121182-04 Name of PI: (Haura) 3/1/07 - 1/31/12Dates: Source: NIH Title: Stat3 in EGFR Driven Non-Small Cell Lung Cancer % Effort: 3% Role: Statistical Co-investigator **Total Direct Costs:** \$175,000

Total Amount of Award:	\$ N/A
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	5P30CA07692-13 (Dalton) 2/1/07 – 1/31/12 NIH/NCI Moffitt Cancer Center and Research Institute Support Grant 11% Biostatistics Core PI \$8,253,224 \$13,641,447
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	1RC2 CA148322-01 (Fenstermacher) 09/29/09 – 08/31/11 NIH/NCI (ARRA) Developing Information Infrastructure Focused on Cancer Comparative Effectiveness 10% Statistical co-investigator \$604,780 \$ N/A
Account: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	 84-15941-01-01 06/01/10 – 05/1/2011 EUSA Pharma (USA), Inc Caphosol for the Reduction of Mucositis in Patients Receiving Radiation Therapy for Head and Neck Cancer 2% Statistical Advisor \$37,125 \$51,975
Account: Name of PI: Dates: Source: Title: Role: Total Direct Cost: Total Amount of Award:	07BR-02 (Sondak) 7/1/07 – 6/30/10 FL Dept. of Health Melanoma SPORE Planning Grant Statistical co-investigator \$286,881 \$ N/A
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs:	R01 30-15775-99-01 (Monteiro) 07/01/09 – 06/30/10 NIH/NCI BRACA-1 Status as a Marker of Clinical Outcome in Lung Cancer 3% Statistical co-investigator \$200,000

Total Amount of Award:	\$ N/A
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:	69-15075-99-01 (Haura) 7/1/07 – 6/30/10 ASCO Targeting EGFR and SRC in Tyrosine Kinase Signaling in Lung Cancer 0.5% Biostatistics Core PI \$414,461 \$ N/A
Account:	R01 CA 105139-01A2
Name of PI:	(Weber)
Dates:	07/01/08 – 05/31/10
Source:	NIH/NCI
Title:	Dendritic cell vaccination during lymphoid reconstitution
% Effort:	20%
Role:	Statistical co-investigator
Total Direct Cost:	\$384,637
Total Amount of Award:	\$ N/A
Account:	7R01 CA109307
Name of PI:	(Weber)
Dates:	09/01/04 – 08/31/09
Source:	NCI
Title:	CTLA-4 Inhibition and Autoimmunity in Melanoma
% Effort:	4%
Role:	Statistical co-investigator
Total Direct Cost:	\$870,431
Total Amount of Award:	\$ N/A
Account:	10-15073-99-01
Name of PI:	(Haura)
Dates:	06/01/07 – 04/30/09
Source:	NIH
Title:	Antitumor Mechanisms of SRC
% Effort:	5%
Role:	Statistical co-investigator
Total Direct Costs:	\$1,265,083
Total Amount of Award:	\$
Account:	U01 CA101222-01
Name of PI:	(Bepler)
Dates:	09/15/03 – 08/31/08
Source:	NCI
Title:	Exisulind for Chemoprevention of Lung Cancer
% Effort:	5%
Role:	Statistical co-investigator
Total Direct Costs:	\$3,089,222

Total Amount of Award: \$5,035,433 1R01 CA 133594 Account: Name of PI: (Djulbegovic) 05/28/07 - 07/31/08 Dates: Source: DOC Quality of Research on Treatment Harms in Cancer Title: % Effort: 3% Statistical co-investigator Role in the Study: Total Direct Costs: \$285,250 Total Amount of Award: \$570,500 R01 CA10272-0101 Account: Name of PI: (Bepler) 07/01/03 - 06/30/08 Dates: Source: NIH RRM1/PTEN Axis in Response and Survival of Non-Small Cell Title: Lung Cancer % Effort: 5% Role: Statistical co-investigator. **Total Direct Costs:** \$1,719,855 \$2,518,983 Total Amount of Award: Account: G1500Z8 (94-14103-99-01) Name of PI: (Anasetti) 04/03/07 - 04/02/08 Dates: Source: Pfizer, Inc. Title: A Retrospective Comparison of Fluconazole with Voriconazole as Fungal Prophylaxis in a Bone Marrow Transplant % Effort: 0.5% **Biostatistics Core PI** Role in the Study: Total Direct Costs: \$80,000 Total Amount of Award: \$ N/A Account: 6302036L0 (Djulbegovic) Name of PI: 09/01/05 - 07/31/07Dates: Source: NIH Title: Evaluation of the Quality of Clinical Trials % Effort: 1% Role: Statistical co-investigator Total Direct Costs: \$350,000 Total Amount of Award: \$450,000 R21 CA110487-01A1 Account: Name of PI: (Bepler) 04/01/05 - 03/31/07Dates: Source: NCI Pharmacogenomics of Neoadjuvant Gemcitabine-Pemetrexed Title: % Effort: 5% Role: Statistical co-investigator

Total Direct Costs: Total Amount of Award:

Account: Name of PI: Dates: Source: Title:

% Effort: Role in the Study: Total Direct Costs: Total Amount of Award:

Account: Name of PI:

Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award:

Completed (Cont.)

Internal Grants:

Account: Name of PIs: Dates: Source: Title:

% Effort: Role in the Study: Total Direct Costs: Total Amount of Award:

Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Total Amount of Award: Effort ended:

Account: Name of PI: \$573,746 R21 CA106166-01 (G. Simon) 06/30/06 – 09/07/06 NCI Molecular Analysis-Directed Individualized Therapy in Advanced Non-Small Cell Lung Cancer 3% Statistical co-investigator \$N/A \$N/A \$N/A P01 CA82533 04 (Sullivan) 05/01/00 – 04/01/06 NCI

MOPP-Clinical Trial Core 5% Head of Biostatistics Core \$1,056,312 \$1,119,815

\$385,718

N/A (Giuliano/Vadaparampil)

01/01/2017 – 01/31/2018 Moffitt Cancer Center, Team Science Reversing the Hepatocelular Carcinoma Trends in Moffitt's Catchment Areas: HVC Screening 9% Co-Investigator \$150,000 \$150,000

n/a (Rollison & Burnette)

11/05/2015 – 02/04/2017 Moffitt Cancer Center, Team Science Immunosuppressive T-cells and Keratinocyte Cancer 2% Co-Investigator \$50,000 \$50,000 2/25/2017 n/a (Giuliano)

Dates:	07/01/2015 – 09/30/2016 Maffitt Cancer Center Miles for Maffitt
Source:	Moffitt Cancer Center, Miles for Moffitt
Title:	Oral Immunological Response to HPV Vaccine: Extending the
	Cancer Prevention Benefits of Vaccination
% Effort:	3%
Role in the Study:	Co-Investigator
Total Direct Costs:	\$100,000
Total Amount of Award:	\$100,000
Account:	n/a
Name of PI:	(Djeu, Brandon & Wei)
Dates:	07/30/2015 - 07/29/2016
Source:	Moffitt Cancer Center, Team Science
Title:	The Role of microRNA-183 in Natural Killer Cell Function
	against Human Lung Cancer
% Effort:	1%
Role in the Study:	Co-Investigator
Total Direct Costs:	\$118,718
Total Amount of Award:	\$118,718

University of North Carolina at Chapel Hill (1995-2005)

External Grants:

Account: Name of PI: Dates: Source: Title: % Effort: Total Direct Costs:	2-U01-CA70040 (Yankaskas) (Schell Co-PI) 10/1/00 – 7/3/05 NCI Breast Cancer Surveillance Research in North Carolina, Part I 5% \$483,652.00
Account:	1 U01-CA70040-06
Name of PI:	(Yankaskas)
Dates:	10/1/00 - 07/31/05
Source:	NCI
Title:	Breast Cancer Surveillance Research in North Carolina, Part II
% Effort:	10%
Role in the Study:	Statistical co-director of this project
Total Direct Costs:	\$33,106.00
Account:	5-P50-CA58223 (Earp, III)
Dates:	8/1/01 - 7/31/06
Source:	NCI
Title:	SPORE in Breast Cancer - Core 4: Biostatistics and
	Bioinformatics Core
% Effort:	10%
Role in the Study:	Director of Core 4
Total Direct Costs:	\$33,106.00
Account:	DAMD17-03-2-0052

Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs:	(Mohler) 9/1/03 – 8/31/06 U.S. Army Medical Research Racial Differences in Prostate Cancer: Influence of Health Care and Host and Tumor Biology, Core 1 - Epidemiology 15% Statistical co-director of this project \$828,010.00
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs:	Not assigned (Baucom) 4/1/04 – 3/31/09 NCI A Couples Approach to Enhance Breast Cancer Survivorship 10% Statistical co-investigator \$494,489.00
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs:	P30-CA16086-31 (Earp, III) 12/1/04 – 11/30/09 NCI Cancer Center Core Support Grant-Biostatistics and Data Management Core 30% Director of Biostatistics and Data Management Core \$390,991.00
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs:	5-P30-CA16086-26 (Earp, III) 12/01/99 – 11/30/04 NCI Cancer Center Core Support Grant- Biostatistics and Data Management Core 30% Director of the Core \$273,763
Account: Name of PI: Dates: Source: Title: % Effort: Role in the Study: Total Direct Costs: Account:	Not Available (Serody) 12/01/01 – 11/30/06 NIH Enhancing DC-based Immunotherapy for Breast Cancer, Clinical Component 5% Statistical co-investigator \$254,004 1 R01-CA65910

Title:Focal Adhesion Kinase T% Effort:5%Role in the Study:Statistical co-investigatorTotal Direct Costs:\$221,484Account:1-P01-CA77739-02Name of PI:(Mohler)	
Dates: 7/01/99 - 6/30/03 Source: NCI	
Androgen Receptor Fund	on to Androgen Independence, Proj 1 ction in Prostate Cancer
% Effort:5%Role in the Study:Statistical co-investigatorTotal Direct Costs:\$250,553	r
Account: 1-P01-CA77739-02	
Name of PI: (Mohler)	
Dates: $7/01/99 - 6/30/03$	
Source: NCI	
Androgen Receptor Fund	on to Androgen Independence, Proj 2 ction in Recurrent Prostate Cancer
% Effort: 2.5%	
Role in the Study:Statistical co-investigatoThe study:\$227.622	r
Total Direct Costs:\$237,663	
Account: 1-P01-CA77739-02	
Name of PI: (Mohler)	
Dates: $7/01/99 - 6/30/03$	
Source: NCI	
Title: Prostate Cancer: Transit Immunoanalysis	ion to Androgen Independence, Core B
% Effort: 2.5%	
Role in the Study: Statistical co-investigator	r
Total Direct Costs:\$181,003	
Account: LCCC 9719	
Name of PI: (Socinski)	
Dates: $1/14/98 - 1/13/03$	
Source: Bristol-Meyers Squibb	
Versus Continuous Adm	rial Comparing a Defined Duration inistration of Combination
% Effort: 5%	
Role in the Study: Statistical co-investigator	r
Total Direct Costs:\$148,483	
Account: TPRH-99-254-01-CCE	

Name of PI: (Godley) 5/01/99 - 4/30/02Dates: Source: American Cancer Society A Case-Control Study of Prostate Cancer Screening Title: % Effort: 5% Role in the Study: Statistical co-investigator **Total Direct Costs:** \$289,000 Account: 00868-02 Name of PI: (Pisano) 8/15/00 - 8/14/02 Dates: Source: NC Department of Health and Human Services Title: Mammography Quality Assurance % Effort: 2% Role in the Study: Statistical co-investigator Total Direct Costs: \$84,636 1-P30-DK56350-01 Account: Name of PI: (Zeisel) 9/30/99 - 9/29/04 Dates: Source: National Inst. of Health Title: Clinical Nutrition Research Unit Core Grant 7.5% % Effort: Role: Director of the Core, 1999-2000 Total Direct Costs: \$932,723 1-R21-CA89961-01 Account: Name of PI: (Serody) 9/30/00 - 9/29/01 Dates: National Cancer Institute Source: Title: Immunotherapy for Metastatic Breast Cancer % Effort: 5% Role: Statistical co-investigator Total Direct Costs: \$180,000 LCCC9904 Account: Namae of PI: (Collichio) 12/01/99 - 7/31/01Dates: Source: **Roche Pharmaceuticals** Title: XEL023 - A Phase I/II Trial of Xeloda, Every 3 Week Taxol, and Herceptin in Metastatic Breast Cancer % Effort: 1.25% Statistical co-investigator Role: Total Direct Costs: \$30,000 00073-99 Account: Name of PI: (Campbell) 10/01/98 - 9/30/00 Dates: US Depart. of Agriculture Source: Colorectal Cancer Prevention in Rural Black Churches Title: 5% % Effort:

Role: Statistical co-investigator Total Direct Costs: \$142,730 Account: N01-CN-75035-70 Name of PI: (Zeisel) 6/01/98 - 9/29/00 Dates: Source: National Cancer Institute Title: Phase I single & multiple-dose safety pharmacokinetic, in women – isoflavone mixtures % Effort: 10% Role: Statistical co-investigator **Total Direct Costs:** \$860,000 RPG-97-110-01-CCE Account: Name of PI: (Dorsey) 7/01/97 - 6/30/01 Dates: American Cancer Society Source: % Effort: 2% Title: p53 Alterations in Benign Breast Lesions and Development of Breast Cancer Role: Statistical co-investigator Total Direct Costs: \$80,000 Account: LCCC9727 Name of PI: (Shea) Dates: 10/31/97 - 9/30/00 Source: AMGEN Inc. Title: Multiple cycles of high dose chemotherapy supported with Filgrastim and peripheral blood cells in patients with metastatic breast cancer. % Effort: 5% Role: Statistical co-investigator **Total Direct Costs:** \$105,000 LCCC 9611 Account: (Socinski) Name of PI: 7/01/97 - 6/30/98Dates: Glaxo-Wellcome Source: Title: Evaluation of oral antiemetic regimens for moderately high to highly emetogenic chemotherapy: pilot study of % Effort: 0% Role: Statistical co-investigator Total Direct Costs: \$240,000 1-P50-CA58223-08 Account: Name of PI: (Earp, III) 9/30/95 - 7/31/01Dates: Source: National Cancer Institute Title: SPORE in Breast Cancer - Data Management Core % Effort: 10% Role: Statistical co-investigator

Total Direct cost:	\$79,693
Account:	1-U01-CA70040-05
Name of PI:	(Yankaskas)
Dates:	9/30/95 – 7/31/00
Source:	National Cancer Institute
Title:	Breast Cancer Surveillance Research in North Carolina -
The.	Subcontract
% Effort:	10%
Role:	Statistical co-investigator
Total Direct Costs:	\$367,670
Total Direct Costs.	\$507,070
Account:	SuperGen
Name of PI:	(Mohler)
Dates:	3/15/98 - 7/15/99
Title:	Project 1: The toxicity and efficacy of Coumarin versus
	advanced kidney and prostate cancer
% Effort:	5%
Role:	Statistical co-investigator
Total Direct costs:	\$109,010
Account:	DAMD17-94-J-4334
Name of PI:	(Yankaskas)
Dates:	9/30/94 - 9/29/98
Source:	U.S. Army Medical Research
Title:	Population-Based Mammography Registry
% Effort:	5%
Role:	Statistical co-investigator
Total Direct Costs:	\$257,860
Univer	rsity of California at Irvine (1991-1995)
Account:	
Name of PI:	(P. Luce-Aoelua)
Dates:	7/01/94 - 6/30/97
Source:	National Cancer Institute
Title:	Cancer Control Needs Among American Samoans
% Effort:	10%
Role:	Statistical co-investigator
Total Cost:	\$1,471,048
10001 0000	<i>4.1,1,1,0,10</i>

Total Cost.	\$1,471,040
Account:	CA-50364
Name of PI:	(M. Berman)
Dates:	9/30/91 - 8/31/96
Source:	National Cancer Institute
Title:	Chemoprevention of Cervical Cancer with Beta-Carotene
% Effort:	15%
Role:	Statistical co-investigator
Total Cost:	\$1,468,509
Account:	NCI P30

Name of PI:	(F. Meyskens)
Dates:	2/01/94 - 1/31/97
Source:	National Cancer Institute
Title:	Center Grant for UCI Cancer Center
% Effort:	50%
Role:	Biostatics Shared Resource Director/Statistical co-investigator
Total Cost:	\$3,174,323

St. Jude Children's Research Hospital, Memphis TN (1984-1991)

- 1) National Cancer Institute Cancer Center Support Grant
- 2) National Cancer Institute Leukemia Program Project Grant (CA20181)
- 3) National Cancer Institute Solid Tumor Program Project Grant

Dissertation

Schell MJ. An increasing failure rate approach to low dose extrapolation.

Service

Moffitt Cancer and Research Center

1. Administrative Appointments:

2005 – Present Director, Biostatistics Shared Resource, H. Lee Moffitt Cancer Center.2013-2014 Interim Chair, Biostatistics and Bioinformatics Department

2. Committees:

2016-present	Biostatistics Core Committee (ex officio)
2015-2016	Behavorial Scientific Review Committee
2014 - present	Biostatistics and Bioinformatics Department Executive Committee
2014 - present	Core Leadership Committee
2013 - 2015	TCC Faculty Advisory Committee
2012 - 2014	Biomarker Validation Committee
2012 - 2014	Personalized Clinical Trials Committee
2011 - 2013	TCC Data Standards & Release Committee
2011 - 2012	Laurel Board Scientific Review Committee
2010 - present	Protocol Monitoring Committee
2010 - 2015	Scientific Review Committee (backup member)
Fall 2008 - 2014	Research Institute Steering Committee (RISC)
Fall 2007 - 2010	Data Quality Executive Committee
Fall 2007 - 2010	Database Stakeholders Committee
12/05 - 2014	Population Science Executive Committee
12/05 - 2014	Scientific Leadership Committee
12/05 - 2014	Bioinformatics Steering Committee
02/06 - 10/06	Protocol Monitoring Committee
12/05 - 9/06	Protocol Review and Monitoring Committee Magnolia
12/05 - 9/06	Scientific Review Committee

12/05 - 4/06	Protocol Review and Monitoring Committee Holly
12/05 - 6/06	Total Cancer Care Data Committee

3. Internal Grant Reviews

ACS-IRG, 2017 (2 reviews) Biostatistics and Bioinformatics Department, 2017 (2 reviews) Skin SPORE, 2017 (2 reviews) FORMA Grant Reivew, 2016 BMS Rare Population Malignancies Program (RPMP), 2015-2016 Skin Spore Grant Reviews, 2014-2016 NFGC Grant Reviews, 2010 ACS-IRG Grant Reviewer, Moffitt Cancer Center, 2006-2007 DIO RAF2 Grant Reviews, Moffitt Cancer Center, 2007

University of North Carolina Service

<u>Department</u> 2004 – 2005 2002 – 2005 1999 – 2000 1998 – 1999 1995 – 1997	Chair, Research Faculty Search Committee Member, Graduate Studies Committee, UNC Chair, Research Faculty Search Committee, UNC Chair, Research Faculty Search Committee, UNC Chair, Biostatistics Seminar Committee, UNC
<u>University</u>	
2002 - 2005	Member, Data and Safety Monitoring Committee
1997 - 2005	Member, Line Berger Comprehensive Cancer Center Program Planning
	Committee
1995 - 2005	Member, Protocol Review Committee, Lineberger Comprehensive Cancer
1005 2005	Center Director of the Directotistics Shared Decourse Linchesser Conversion Converse
1995 – 2005	Director of the Biostatistics Shared Resource, Lineberger Comprehensive Cancer Center, 1995-2005
Profession :	
State	
2000	President of the North Carolina Chapter of the American Statistical Association
1987 - 1990	President of the Western Tennessee Chapter of the American Statistical
	Association
1986 - 1987	Secretary of the Western Tennessee Chapter of the American Statistical
1005 1000	Association
1985 – 1986	Secretary/Treasurer of the Western Tennessee Chapter of the American Statistical Association
	Staustical Association

National

2017	Second Annual Statistical Practice in Cancer Conference, March 3, 2017 Moffitt Cancer Center (Conference Organizer)
2016	First Annual Statistical Practice in Cancer Conference, May 13, 2016 Moffitt Cancer Center (Conference Organizer)
2011	Conference on Statistical Practice Organizing Committee

2007 – 2008	Program Chair for 2008 Joint Statistical Meetings, Statistician Sports Section, American Statistical Association
2008	Organizer of one of two "Late Breaking Sessions" for the Joint Statistical Meetings (upon the invitation for overall JSM organizer, Dr. Russell Lenth) on Steroids and Baseball
2005 - 2006	Present Statistical Editor, Cancer Control
2005 - 2007	Vice Chair, Council of Chapters Governing Board, District 5 (Southeast, US.) American Statistical Association
2003	President, Statistics in Sports Section of the American Statistical Association
1999 - 2001	Statistics Section Council, American Public Health Association (1999-2001)

Manuscript Reviewer

Medical – Journal of Clinical Oncology, Medical and Pediatric Oncology, European Journal of Cancer, Health Education Research, Lung Cancer, Public Health Nutrition, Cancer Prevention and Detection, Archives of Environmental Contamination and Toxicology, BMC Medical Informatics and Decision Making, Therapeutic Innovation and Regulatory Science

Statistical – Journal of the American Statistical Association, Biometrics, Statistics in Medicine, Computational Statistics and Data Analysis, American Statistician, Drug Information Journal, Statistical Modeling, Cancer Control Journal, Clinical Trials and Scientometrics

2018	JNCI Gut Int J of Tech Assessment JNCI BMC Medical Genetics BMC Med Inf &Dec Making	March March July August August
2017	Oncotarget Clinical Trials PloS1 Future Oncology JNCI Int J Tech Assessment Scientific Reports Gastrointestinal Res & Pract	January June September October October November November November
2016	Oncogene JNCI Oncotarget Cancer Biomarkers	May, June October November December
2015	PLoS One Nucleic Acids Research JAMA-Oncology	January August, December June
2014	Statistics in Medicine PLoS One Scientometrics	February August, September September

2013 Statistics in Medicine April, June, N	
Clinical Trials June Therapeutic Innovations April	November

Book - Johns Hopkins University Press, Oxford University Press, Princeton University Press

Grant Reviewer

Biostatistical Methods and Research Design (BMRD) Section, March, 2017

NCI (CISNET) Cancer Interventional Surveillance Monitoring Network, April, 2015

CDMRP-CRMRP-RTRA-PCS-2 grant review (12 grant reviews)

Israel Science Foundation, online review, February, 2014

Member, Cancer Biomarkers Study Section, July, 2010 – February 2014 (3 review meetings/year)

Cancer Biomarkers Study Section (ad hoc member), October, 2009

Susan Koman Grants, September, 2009

NCI Challenge Grants, June, 2009

Susan Koman Breast Cancer Grants, November, 2008

NCI Nanotechnology Grant, July 2005

NCI/Avon Breast Cancer Grant, January, 2003; January, 2005

NCI PO1 Grants, October, 2002; January, 2003; August, 2003; October, 2003; December, 2003

NCI Cancer Center Core Grant, October, 2002

NCI CONC Review Group, July, 2002

NCI (CISNET) Cancer Interventional Surveillance Monitoring Network, Second Round, March, 2002

NCI (CISNET) Cancer Interventional Surveillance Monitoring Network, First Round, March, 2000

Review Boards

2005	Member, Data and Safety Monitoring Board, for the NCI-funded clinical trial: An International multicenter phase III study of chemoradiotherapy plus hyperthermia for locally advanced cervical cancer. PI: Mark Dewhirst, M.D., Duke University.
2004 - 2005	Member, External Advisory Committee for the Carolina Center for Aids Research (CFAR).

Data Safety Monitoring Board

2015-present Testosterone Plus Finasteride Treatment afte Spinal Cord Injury, North Florida/South Georgia Veterans Health System, Study # B1449-01, Dr. Joshua Yarrow (PI)

Professional Association Memberships

- 1999 present Member, Delta Omega Theta Chapter
- 1984 present Member, American Statistical Association
- 1981 present Member, Biometric Society
- 1993 2001 Member, Sigma Xi
- 1999 2001 Member, American Public Health Association
- 1979 1981 Member, Pi Mu Epsilon

External Review for Promotion and/or Tenure

- 2016 University of California-Irvine Georgetown University Fox Chase Cancer Center
- 2015 University of Kentucky University of New Mexico Vanderbilt University Boston University
- 2014 Georgetown University University of South Florida Emory University
- 2013 University of Hawaii Cancer Center Harvard University University of Miami Oregon Health & Science University Georgetown University
- 2011 University of South Florida
- 2010 Georgetown University Medical University of South Carolina
- 2009 Moffitt Cancer Center
- 2008 University of Hawaii at Manoa Syracuse University
- 2007 Wayne State University

Peer-Reviewed Research Articles

- <u>Schell MJ</u> and Singh B. Robustness of X² and E²: A case for a ranked test in orderrestricted inference. Advances in order restricted inference. Eds. R. Dykstra, T Robertson and F.T. Wright. *Springer-Verlag 1986*; pp. 184-202
- 2. Meyer WH, **Schell MJ**, Kumar APM, Rao BN, Green AA, Champion J, Pratt CB. Thoracotomy for pulmonary metastatic osteosarcoma. *Cancer* 1987; 59:374-379
- 3. Hughes WT, Rivera GK, **Schell MJ**, Thornton D, Lott L. Successful intermittentchemoprophylaxis for <u>pneumocystis carinii</u> pneumonitis. *N Engl J Med* 1987 Jun; 316:1627-1632. PMID: 3495732

- 4. Ribiero RC, Pui C-H and **Schell MJ**. Vertebral collapse as a presenting feature of acute lymphoblastic leukemia in children. *Cancer* 1988 Feb; 61:589-592. PMID: 3276382
- 5. Pui C-H, Kalwinsky DK, Schell MJ, Mason CA, Dahl GV. Acute nonlymphoblastic leukemia in infants: Clinical presentation and outcome. *J Clin Oncol 1988;* 6:1008-1013
- 6. Kalwinsky D, Mirro J, **Schell MJ**, Behm F, Mason C, Dahl GV. Early intensification of chemotherapy for childhood acute nonlymphoblastic leukemia: Improved remission induction with a five-year regimen including etoposide. *J Clin Oncol* 1988; 6:1134-1143
- 7. <u>Schell MJ</u> and Morrison M. A statistical model for the timing mechanism of the erythrocyte life span (with commentary). *Blood Cells* 1988; 14:297-311. PMID: 3179458
- 8. Lauer ME, Mulhern RK, **Schell MJ**, Camitta BM. Long-term follow up of parental adjustment following a child's death at home or hospital. *Cancer* 1989; 63:988-994
- 9. Carter M, Kalwinsky DK, Dahl GV, Santana V, Mason CA, **Schell MJ**. Childhood acute promyelocytic leukemia: a rare variant of nonlymphoid leukemia with distinctive clinical and biologic features. *Leukemia* 1989 Apr; 3:298-302. PMID: 2927178
- Hutchison RE, Kunkel KD, Schell MJ, Jackson CW, Nelson EJ, Wang WC, Fischl SJ, Taylor LB, Garcez RB, Pui C-H. Beneficial effect of brief pre-transfusion incubation of platelets at 37 degrees C. *Lancet* 1989 May; i:986-988. PMID: 2565517
- 11. <u>Schell MJ</u>, McHaney VA, Green AA, Kun LE, Hayes FA, Horowitz M,Meyer WH. Hearing loss in children and young adults receiving cisplatin with or without prior cranial irradiation. *J Clin Oncol* 1989; 7:754-760
- Pinto A, Grant LH, Hayes FA, Schell MJ, Parham DM. Immunohistochemical expression of neuron-specific enolase and Leu 7 in Ewing's sarcoma of bone. *Cancer* 1989 Sep; 64:1266-1273. PMID: 2670185
- 13. <u>Schell MJ</u> and Leysieffer FW. An increasing failure rate approach to low dose extrapolation. *Biometrics* 1989; 45:1117-1124.
- 14. Ribeiro RC, Sandrini R, **Schell MJ**, Lacerda L, Sambaio GA, Cat I. Adrenocortical carcinoma in children: study of 40 cases. *J Clin Oncol* 1990 Jan; 8:67-74,. PMID: 2295912
- Kalwinsky DK, Raimondi SC, Schell MJ, Mirro J, Santana VM, Behm F, Dahl GV, Williams D. Prognostic importance of cytogenetic subgroups in de novo pediatric acute nonlymphocytic leukemia. *J Clin Oncol* 1990 Jan; 8:75-83. PMID: 2295913
- Pui C-H, Behm FG, Singh B, Schell MJ, Williams DL, Rivera GK, Kalwinsky DK, Sandlund JT, Crist WM, Raimondi SC. Heterogeneity of presenting features and their relation to treatment outcome in 120 children with T-cell acute lymphoblastic leukemia. *Blood* 1990 Jan; 75:174-179. PMID: 2136802
- 17. Pui C-H, Behm FG, Singh B, Rivera GK, **Schell MJ**, Roberts WM, Crist WM, Mirro J. Myeloid-associated antigen expression lacks prognostic value in childhood acute

lymphoblastic leukemia treated with intensive multiagent chemotherapy. *Blood* 1990 Jan; 75:198-202. PMID: 2294988

- Dahl GV, Kalwinsky DK, Mirro J, Look AT, Mason C, Schell MJ, Johnson FL, Thomas ED. A comparison of intensive post-remission chemotherapy or allogeneic bone marrow transplantation to prevent initial leukemia relapse in childhood acute nonlymphocytic leukemia. J Clin Oncol 1990; 8:295-303
- Koehler M, Schell MJ, Behm FG, Raimondi SC, Woodruff LS, Mirro J. Expression of a novel surface antigen MKW in childhood acute leukemia has prognostic significance. *Leukemia* 1991 Jan; 5:41-48. PMID: 1999957
- 20. Wang W, Kovnar E, Tonkin I, Mulhern R, Langston J, Day S, **Schell M**, Williams J. High risk of recurrent stroke after stopping transfusion therapy in sickle cell patients transfused for 5-12 years. *J Peds* 1991; i:377-382
- Schriock EA, Schell MJ, Carter M, Hustu O, Ochs JJ. Abnormal growth patterns and adult short stature in long-term survivors of childhood leukemia. *J Clin Oncol* 1991 Mar; 9:400-405. PMID: 1999710
- 22. Santana VM, Mirro J, Harwood FC, Cherrie J, **Schell M**, Kalwinsky D, Blakley RL. A phase I clinical trial of 2-chlorodeoxyadenosine in pediatric patients with acute leukemia. *J Clin Oncol* 1991 Mar; 9:416-422. PMID: 1671875
- 23. Mahmoud H, Schell M, Pui C-H. Cholelithiasis after cancer treatment. *Cancer* 1991; 67:1439-1442
- Pui C-H, Schell MJ, Vodian MA, Kline S, Mirro J, Crist WM, Behm FG. Serum CD4, CD8 and interleukin-2 receptor levels in childhood acute myeloid leukemia. *Leukemia* 1991 Mar; 5:249-254. PMID: 1901614
- 25. Pui C-H, Raimondi SC, Head DR, **Schell MJ**, Rivera GK, Mirro J, Crist WM, Behm FG. Characterization of childhood acute leukemia with multiple myeloid and lymphoid markers at diagnosis and at relapse. *Blood* 1991 Sep; 78:1327-1337. PMID: 1878594
- 26. Relling MV, Cherrie J, **Schell MJ**, Petros WP, Meyer WM, Evan WE. Lower prevalence of the debrisoquin oxidative poor metabolizer phenotype American black versus white subjects. *Clin Pharmacol Ther* 1991 Sep; 50:308-313. PMID: 1680593
- Rao BN, Santana VM, Parham D, Pratt CB, Fleming ID, Hudson M, Fontanesi J, Philippe P, Schell MJ. Pediatric non-rhabdomyosarcomas of the extremities. *Arch Surg* 1991; 126:1490-1495
- Schell MJ, Ochs JJ, Schriock EA, Carter M. A method of predicting adult height and obesity in long-term survivors of childhood acute lymphoblastic leukemia. J Clin Oncol 1992 Jan; 10:128-133. PMID: 1727914
- 29. Bean WJ, **Schell M**, Katz J, Kawaoka Y, Naeve C, Gorman O, Webster RG. Evolution of the H3 influenza virus hemoagglutinin from human and nonhuman hosts. *J of Virol* 1992 Feb; 66:1129-1138. PMCID: PMC240817

- Eguiguren JM, Schell MJ, Crist WM, Kunkel K, Rivera GK. Complications and outcome in childhood acute lymphoblastic leukemia with hyperleukocytosis. *Blood* 1992 Feb; 79:871-875. PMID: 1737097
- 31. Behm FG, Raimondi SC, **Schell MJ**, Look AT, Rivera GK, Pui C-H. Lack of CD45 antigen on blast cells in childhood acute lymphoblastic leukemia is associated with chromosomal hyperdiploidy and other favorable prognostic features. *Blood* 1992 Feb; 79:1011-1016. PMID: 1531305
- Hurwitz CA, Schell MJ, Pui C-H, Crist WM, Behm F, Mirro J. Adverse prognostic features in 251 children treated for acute myeloid leukemia. *Med Pediatr Oncol* 1993; 21:1-7. PMID: 8426571
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Letters to the Editor, Comments

- 1. Reply to letter to the editor regarding "Hearing loss in children and young adults receiving cisplatin with or without cranial irradiation". *J Clin Oncol* 8:180, 1990.
- 2. Evans WE, **Schell MJ** and Pui C-H. MTX clearance is more important for intermediate-risk ALL. Letter to the editor. *J Clin Oncol* 8:1115-1116, 1990.
- 3. Pui C-H, **Schell MJ**, Raimondi SC, Head DR et al. Myeloid-antigen expression in childhood acute lymphoblastic leukemia. *N Engl J Med* 325:1378-1379, 1991. (letter.)

- 4. <u>Schell MJ</u>. Comment on "Bridging different eras in sports" *J Am Statist Assoc*, 94:681-684, 1999.
- Bert H. O'Neil, MD, Michael Schell, PhD, Richard M. Goldberg, MD. Synchronous Colorectal Cancers: What's the Risk? *Clinical Advances in Hematology & Oncology*, 2(2), February 2004.
- 6. Yankaskas BC, Schell MJ, Miglioretti DL. Recall and detection rates in screening mammography (letter). *Cancer* 101(11):2710-2711, 2004.

Books

- 1. <u>Schell MJ</u>. Baseball's All-Time Best Hitters: How Statistics Can Level the Playing Field, Princeton University Press, 1999, 295 pp.
- <u>Schell MJ</u>: Baseball's All-Time Best Sluggers: Adjusted Batting Performance from Strikeouts to Home Runs. Princeton University Press, 2005, 416 pp.

Technical Reports

- 1. Schell MJ and Leysieffer FW. Bivariate low dose extrapolation. Florida State University Statistics Report M762. July, 1987.
- 2. Schell MJ and Singh B. Power functions of likelihood ratio tests under order restrictions in normal means with three or four treatments. St. Jude Children's Research Hospital. Technical Report # 4, June, 1988.
- 3. Singh B, **Schell MJ** and Wright FT. The power functions of the likelihood ratio test for a simple tree order in normal means. St. Jude Technical Report # 5, December, 1988.
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Book Chapters

- 1. Mirro J, Crom W, Santana VM, **Schell MJ**, Belt J, Fridland A and Kalwinsky DK. AML trials at St. Jude Children's Research Hospital. *In*: Acute Myelogenous Leukemia: Progress and Controversies, R Gale (ed.). Wiley-Liss, New York, NY, pp. 219-227, 1990.
- Kalwinsky DK, Raimondi SC, Schell MJ, Behm FG and Mirro J. Cytogenetic abnormalities in childhood AML. *In*: Acute Myelogenous Leukemia: Progress and Controversies, R Gale (ed.). Wiley-Liss, New York, NY, pp. 133-139, 1990.
- 3. Meyer WH, Pratt CB, **Schell MJ**, Fletcher BD, Marina N, Parham DM, Rao BN, Sandlund JT and Dahl G. The uses of ifosfamide as initial therapy in osteosarcoma. *In*: Adjuvant therapy of cancer, Volume 6, SE Salmon (ed.). WB Saunders, Philadelphia, PA, pp. 580-585, 1990.

- 4. McHaney V, Kovnar E, Meyer W, Furman W, **Schell M** and Kun L. Effects of radiation therapy and chemotherapy on hearing. *In*: Late effects of treatment for childhood cancer. DMGreen GJ D'Angio, (eds.). Wiley-Liss, New York, NY, pp. 7-10, 1992.
- Haier RJ, Hazen K, Fallon J, Alkire MT, Schell MJ and Lott I. Brain imaging and classification of mental retardation. *In*: Perspectives on fundamental processes in intellectual functioning. S Soraci and WJ McIlvane, (eds.) Ablex Publishing, Stamford, CT, pp. 115-130, 1998.
- Schell MJ, McBride MA, Gennings C and Koch GG. The intention-to-treat principle for clinical trials. *In*: Clinical trials in neurology, RJ Guiloff, (ed.). Springer London, pp. 131-144, 2001.

Book Reviews

- 1. <u>Curve Ball</u> (J Albert, J Bennett, Authors) Spinger-Verlag, 2001, New York. *Journal of the American Statistical Association* 2002, pg. 919.
- 2. <u>Teaching Statistics Using Baseball (J Albert, Author)</u> The Mathematical Association of America, 2003, Washington, D.C. *Mathematical Intelligencer*, 2005.

Research Interests

Monotonic and nonparametric regression analysis, piecewise linear regression, changepoint analysis, order restricted inference, practice of statistics, cancer research.

Software

An important aspect of introducing new statistical methods into practice is having user-friendly software available to the user. The following SAS macros are available to users or in development:

REDMON – (Programmer: Sean O'Brien) Obtains reduced monotonic regression estimates for a standard regression setting with a continuous dependent variable given. The theoretical underpinnings are given in Schell and Singh, 1997. Since 1998, over 300 individuals have accessed this macro. 15 page user's guide available. REDMON has been applied to real data in 5 published articles to date.

BREDMON – (Programmer: Sean O'Brien) Reduced monotonic regression for a binary dependent variable. A slight extension of theory from Schell and Singh, 1997.

ISO2VAR – (Programmer: Dan Scharf) An extension of reduced monotonic regression to the matrix order. A 24-page user's guide is available.

Two additional SAS macros, PIECELIN and MULTI-CHANGEPT, are currently under development as well.

Invited Lectures

1. "Long-Term Effects to Treatment of Acute Lymphocytic Leukemia," Pediatric Cancer Family Retreat, October, 1992.

- 2. "Elements of Statistics and Avoiding Data Pitfalls," FHP Research Day, March, 1993.
- 3. "Survival Analysis," Long Beach Memorial Hospital, March 1994.
- 4. "Regression Analysis," Long Beach Memorial Hospital, March 1994.
- 5. "Statistics in Cancer Research," a lecture to Cancer Education Program (CEP) students, Summer 1997-1999. (3 times)
- 6. "Tony Gwynn Baseball's Best Pure Hitter: A Statistical Analysis," University of North Carolina, September 17, 1997.
- Book signings for "Baseball's All-Time Best Hitters," at Waldenbooks, Chapel Hill;
 Barnes & Noble, Durham; Regulator Bookshop, Durham; Barnes & Noble, Philadelphia.
- 8. Thirty-five radio and newspaper interviews on "Baseball's All-Time Best Hitters."
- 9. "Discussant for "Bridging Eras in Sports," American Statistical Association, Joint Statistical Meetings, September, 1999.
- 10. "Baseball's All-Time Best Hitters," University of North Carolina Teague Residence Hall, April 4, 2000.
- 11. "Baseball's All-Time Best Hitters," Fortieth Anniversary of the Statistics Department of Florida State University, April 21, 2000.
- 12. "Baseball's All-Time Best Hitters," University of South Carolina, March, 2001.
- "Identifying a Target Recall Rate in Screening Mammography Using Reduced Monotonic Regression", Breast Cancer Surveillance Consortium Meeting, Santa Fe, NM, April 21, 2001.
- 14. "Statistical Issues in Clinical Trials," part of a Clinical Trials workshop for Oncology Fellows, Duck, NC, October, 2001.
- 15. "Association of Recall Rates with Sensitivity and Positive Predictive Values of Screening Mammography", Breast Cancer Surveillance Consortium Meeting, April 20, 2002.
- 16. "Do Statisticians Care How Users Analyze The Two-Sample Location Problem?", Duke University, May 15, 2002.
- 17. "Identifying the Best Home Run Parks in Baseball History", Statistics in Sports section of the ASA, Joint Statistical Meetings, August 12, 2002.
- "Identifying Monotonic Trends in Data," Virginia Commonwealth University, February 18, 2003.
- "Identification of Ideal Recall Rates for Screening Mammography," ENAR, Biometrics Society, Austin, TX, March, 2005.
- 20. "Identification of Ideal Recall Rates for Screening Mammography," Joint Statistical Meeting, August, 2005.
- 21. "Baseball's Best Batters: A Comparison of Models," Roundtable luncheon, Statistics in Sports Section, Joint Statistical Meetings, August, 2005.
- 22. "Piecewise Linear Regression," Korean-American Conference, Irvine, CA, August, 2005.
- 23. "Using Transformations to Obtain Improved Statistical Power," Grand Rounds in Population Science Series, Moffitt Cancer Center, October 2006.
- 24. "Screening Mammography and Best Ballparks for Home Run: Using Flexible Regression Approaches to Obtain Improved Estimation," North Texas Chapter of the American Statistical Association, Dallas, Texas, November 2006.

- 25. "Analysis of a small number of continuous biomarkers for identification of an efficacious drug-treatment response for individual patients," ASCO, Chicago, IL, May 2008.
- 26. "Coors Field: Why Is The Home Field Advantage So High and What are its Implications," Joint Statistical Meetings, Denver, CO, August 2008.
- 27. "Comparing Power Hitters Across Baseball History," part of Steroids and Baseball Late-Breaking Session. Joint Statistical Meetings, Denver, CO, August 2008.
- 28. "Engaging in Statistical Practice in Academia is Honorable." The 50th Anniversary Celebration of FSU's Statistics Department, Tallahassee, FL. April, 2009.
- 29. "Improved Survival Modeling Using A Piecewise Exponential Approach," Joint Statistical Meetings, Washington, D.C., August, 2009.
- 30. "Understanding Biomarker Data from Tissue Microarrays and Parametric Modeling of Survival: How Statistical Thinking Can Help the Oncologist," Fox Chase Cancer Center, Philadelphia, PA, April, 2010.
- 31. "Identifying Key Advances to Improve Statistical Practice", Statistical Practice in Cancer Conference, Moffitt Cancer Center, Tampa, FL, May, 2016
- 32. "Identifying Statistical Innovations Ready for Practice From The Literature", Statistical Practice in Cancer Conference, Moffitt Cancer Center, Tampa, FL, March, 2017