

BIOGRAPHICAL SKETCH

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NAME: Einstein, Mark H.

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

POSITION TITLE: Professor and Chair, Department of Obstetrics, Gynecology & Reproductive Health;
Associate Dean, Clinical Research Rutgers New Jersey Medical School

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Miami, Coral Gables, FL	BS	12/1989	Biology
University of Miami School of Medicine, Miami, FL	MD	05/1995	Medicine
Saint Barnabas Medical Center, Livingston, NJ	Residency	06/1999	Obstetrics & Gynecology
Albert Einstein College of Medicine / Montefiore	Fellowship	06/2002	Gynecologic Oncology
Albert Einstein College of Medicine, Yeshiva	MS	06/2005	Clinical Research Methods

A. Personal Statement

I am a Gynecologic Oncologist and clinician-scientist. My primary research interests focus on the pathogenesis, therapy, and prevention of HPV-associated diseases. I hold many leadership roles in clinical and translational trials. Additionally, I have been funded by the NIH and others for many efforts identifying unique, potentially druggable, targets and biomarkers for HPV-associated diseases. I have developed and lead numerous multi-institutional clinical trials not only for HPV, but for other gynecologic therapeutics. Formally, I was Vice Chair for Research in the Dept. of OB/GYN at Albert Einstein College of Medicine. While there, I reorganized clinical research operations in Women’s Health across the system. Currently, as an Associate Dean of Clinical Research at NJMS, where I oversee operationalization, workflow, regulatory issues and financial issues related to clinical research across the clinical Departments at NJMS. In my leadership roles, including previously being the co-PI on the institutional K-award for cancer at Einstein (Calabresi), I have mentored dozens of clinician-scientist trainees and have served in many leadership roles for clinical trials operations. I am a surgeon-scientist with broad leadership skills and deep understanding of clinical and translational research operations and cooperative group trials. I am also the NJ ACTS (Rutgers CTSA) Associate Director, overseeing the clinical research aspects across local and network hospitals. I will work with the leadership to continue to offer service as described in the CCSG. I will continue to work across cores on amplifying the reach of clinical research across sociodemographically diverse populations like I have done with my broad experience implementing and operationalizing protocols locally, nationally, and internationally.

Ongoing and Recently Completed Projects I would like to highlight include:

NIH/NCATS UL1 TR003017
Panetteri (PI), Role: Associate Director, Core Leader 03/07/2019-03/06/2024
New Jersey Alliance for Clinical and Translational Science (NJ ACTS)
In this role, I oversee operations for clinical trials and recruitment in population dense NE NJ.

U54 CA242639-01 NIH/NCI (Cornell, PI Wilkin)
Cascade Network Subaward with Weill Cornell 9/20/2022-5/31/2027
“Partnership for Advancing Cervical Cancer Prevention in Women Living with HIV”

Role: Dr. Einstein is Assisting Weill Cornell Medicine with the development of the ‘Partnership for Advancing Cervical Cancer prevention in Women living with HIV’ clinical trial and provide periodic scientific input into the design of the other two clinical trials.

R01 MD016280-01A1 NIH/NCI (NWU, PI M. Simon)

Northwestern University NIH Subaward

08/24/2021-04/30/2026

“Enhancing Perinatal Care Support to Improve Maternal Mortality Disparities”

Role: Co-PI of site

This grant supports novel approaches to improving morbidity and mortality of BIPOC women in underserved communities.

U01 CA121947 NIH/NCI (UCSF, PI Palefsky)

AMC- ANCHOR NCI 2UM1CA121947-14 (Co-I, Site PI, M. Einstein)

07/01/2019-09/30/25

AIDS Malignancy Consortium, ANCHOR, Anal Cancer Prevention Study.

Treatment of anal high-grade squamous intraepithelial lesions (HSIL) will lead to a reduction of 75% of incident anal cancer compared with a population with anal HSIL that is observed without treatment.

U54 CA242639-03 NIH/NCI (Cornell, PI Wilkins)

US-Latin American-Caribbean HIV/HPV Cancer Network (ULACnet)

Weill Medical College of Cornell University Sub Award

9/20/19-7/31/24

Partnership for Prevention of HPV- Associated Cancers in People living with HIV: Brazil, Mexico and Puerto Rico.

Role: (Co-I) Dr. Einstein will assist Weill Cornell Medicine with development of the clinical trial and provide periodic scientific input into the design of the other two clinical trials.

Completed Research Support:

NIH/NCI 1R44CA206606 (SBIR) (PI D. Meruelo, NYU- Rutgers PI M. Einstein)

9/1/16-8/31/20

A Phase I Dose-escalation Study of Intraperitoneal CYN101 as Consolidation Immunotherapy in Women with Residual or Recurrent Ovarian Cancer Status after Chemotherapy.

Dr. Einstein is one of the lead PIs on this trial and wrote part of the grant. As per SBIR funding structure, the award will also be sponsored by Cynvec, who will also be contributing substantial funds to the effort.

UG1 CA189859 NIH/NCI (MPI Sparano/Einstein/Rapkin)

8/1/14-7/31/19

NCI Community Oncology Research Program (NCORP)

Minority/Underserved Sites (UM1)-

The overall goals of the Montefiore Medical Center (MMC) minority-based NCORP community site are to advance the diagnosis, prevention, and management of early and advanced cancer by participating in the NCORP as a minority/underserved community site. Role: Used to be co-PI. M. Einstein now consultant since move to Rutgers NJMS

K12 CA132783 NIH/NCI (MPI Perez-Soler, Einstein)

7/1/15-6/30/20

Paul Calabresi Career Development Award for

Clinical Oncology (K12)

This is a competing renewal for our Calabresi K12 funding for Clinician-Scientists in Oncology. Role: Used to be co-PI. M. Einstein now consultant since move to Rutgers NJMS.

B. Positions, Scientific Appointments, and Honors

Positions

7/99-12/02

Instructor, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology. Albert Einstein College of Medicine (AECOM) and Montefiore Medical Center (MMC).

1/03-6/08

Assistant Professor, Division of Gynecologic Oncology, AECOM/MMC

7/03-8/08

Chief of Service, Gynecologic Oncology, Jacobi Medical Center, North Bronx Health Network

7/05-6/13

Director, Clinical Research, Division of Gynecologic Oncology. Montefiore Medical Center

7/07-11/15

Tenure Track Appointment, Albert Einstein College of Medicine.

7/08-6/13

Associate Professor, Dept. of Obstetrics & Gynecology and Women’s Health, AECOM/MMC

7/08-6/13	Director of Clinical Research for Women's Health and Gynecologic Oncology, AECOM/MMC
7/13-11/15	Professor and Vice Chair for Research, Dept. of Obstetrics & Gynecology, AECOM/MMC
11/15-11/16	Adjunct Professor, Depts of OB/GYN and Epidemiology, AECOM
11/15-present	Professor and Chair, Dept. of Obstetrics, Gynecology & Women's Health, Rutgers New Jersey Medical School.
11/15-present	Assistant Dean, Clinical Research Unit, Rutgers New Jersey Medical School.

Honors

2003	CREOG National Faculty Award in Obstetrics and Gynecology for Resident Teaching
2008	American Cancer Society Research Scholar Awardee
2003, 05, 09, 11, 12, 13	Henry L. Moses Award (for best published paper at Montefiore Medical Center)
2012	Albert Einstein College of Medicine National Women's Division 'Spirit of Achievement' award for outstanding research in cancers that affect women
2014	ASCCP Meritorious Service Award

Scientific Appointments

Other Experience and Professional Memberships

Professional Memberships: Diplomate, American Board of Obstetrics and Gynecology (2003); 2005 Diplomate, American Board of Obstetrics and Gynecology- Gynecologic Oncology (2005); Fellow, American College of Obstetrics and Gynecology (03-), Fellow, American College of Surgeons (06-). Full Member of SGO, ASCO, AACR, ASCCP, American Gynecological and Obstetrical Society (AGOS, an honorary society where members composed of individuals attaining national prominence in OB/GYN).

National Organization Leadership Roles: Society of Gynecologic Oncology (SGO) Board of Directors (15-17), ASCCP Board of Directors (10-23); ASCCP President (20); Gynecologic Cancer Foundation (GCF)/Foundation for Women's Cancers(FWC) Board of Directors (07-13); ASCCP Practice Committee co-Chair (10-17); ASCCP Development Committee Chair (12-); Vice-Chair SGO Education Committee (07-08); Member, SGO Marketing & Communications Committee (11-14); Member, SGO Nominating Committee (12-13); Committee Chair National Cervical Cancer Public Education Campaign (06-12); Member, SGO Education Committee (06-10); GCF Chair for SGO GynecoLogic Educational Committee (Cervix) (10-11); Member, SGO Annual Meeting 2009 Program Committee (08-09); Member, SGO Government Relations Committee (05-09); Member, Society of Gynecologic Oncologists (SGO) Candidate Member's Committee (05-07); Member, SGO Educational Resource Panel, HPV and Cervical Cancer (05-07).

Other Professional Activities: Steering committee member ASCCP Cervical Cancer Management Guidelines (12-14); Co-Chair, Gynecologic Oncology Group (GOG) Immunotherapy Committee (08-18), Member, GOG Cervix Committee (08-14); Member, Cervix Working Group of the Cancer Genome Atlas Project (09-13); Co-Chair, Colposcopy Standards Guidelines ASCCP (15-17); Consultant, World Health Organization, developing modules on immunologic basis of HPV vaccines (08-); Co-Chair, International Papillomavirus (IPV) Meeting Clinical Sessions (11-12); Member, American Cancer Society HPV Vaccine/Screening Guidelines Panel (05-06); ACS/NCI/ASCCP Cervical Cancer Screening Update, member of workgroup and data abstraction committee (10-12); NIH Aids Malignancy Consortium (AMC), HPV Working Group (03-) and International Resource Committee (09-); Member, New York Cancer Consortium (NYCC) Steering Committee and co-chair of the Gynecology Working Group (06-14); NCI Translational Research Working Group Roundtable, SGO Representative (12/05, 10/06); Johns Hopkins Cervical Cancer SPORE Advisory Committee (08-).

Peer Reviewer for Domestic and International Funding Sources: NCI PREVENT Cancer Prevention Development Program Study Section Member (11-); Patient Care Oriented Research Institute (PCORI) Study Section Member (2012-); NIH/NCI Chemoprevention Agent Development Research Group to the Rapid Access to Preventative Intervention Development (RAPID) program working group (10-21); Extramural Reviewer Prevention Program (2017-); AHRQ Healthcare Horizon System Expert Reviewer (11-12); External Peer reviewer for the following countries: UK (NAEDI) project (10-12); Singapore Biomedical Research Council- Translational Clinical Sciences Group (10-); South Africa (MRC, 13); Ireland (HRB, 12); Israel Cancer Research Fund (ICRF, 13-17).

C. Contributions to Science

1. My translational work in cervical cancer is multi-faceted. I have investigated the host and virally-induced epigenetic, genetic and immune profiles along the malignant transformation path to provide insight into the process of cervical carcinogenesis in heterogeneous populations.
 - **Einstein MH**, Studentsov YY, Ho G, Fazzari M, Kadish AS, Goldberg GL, Runowicz CD, Burk RD. Human Papillomavirus-Like Particle Serologic Assay to Identify Women At-Risk for High-Grade Cervical Intraepithelial Neoplasia. *Int J Cancer*. 120(1): 55-59. 2006. PMID: 17036320
 - Mhatre M, McAndrew T, Carpenter C, Burk RD, **Einstein MH***, Herold BC* (*Contributed Equally). Changes in Genital Tract Soluble Mucosal Immune Environment in CIN: Insights into the Biological Synergy between HPV and HIV. *STD*. 39(8):591-7. 2012. PMID: 22801340.
 - Wijetunga NA, Belbin TJ, Burk RD, Whitney K, Abadi K, Greally JM, **Einstein MH***, Schlecht NF* (* denotes co-senior authors). Novel Epigenetic Changes in CDKN2A are Associated with Progression of Cervical Intraepithelial Neoplasia. *Gynecol Oncol*. 2016. 142(3): 566-73 PMID: 27401842
 - Wijetunga NA, Ben-Dayan MM, Tozour JN, Burk RD, Schlecht NF, **Einstein MH***, Greally J* (* denotes co-senior authors). A polycomb-mediated epigenetic field defect precedes invasive cervical carcinoma. *Oncotarget*. 2016 Aug. epub PMID: 27557505
2. I am an active member of National Cooperative Groups (NRG Oncology, nCORP) and have been Co-Chair of the Gynecological Cancer Workgroup of the New York Cancer Consortium and NY GOG and the PI of many of its gynecologic cancer therapeutics trials accruing patients throughout New York hospitals. Additionally, I am leading the AMC efforts in cervical cancer treatment in sub-Saharan Africa, focusing on heterogeneity of treatment response.
 - Kuo DY, Blank SV, Christos PJ, Kim M, Caputo TA, Pothuri B, Hershman D, Goldman N, Ivy PS, Runowicz CD, Muggia F, Goldberg GL, **Einstein MH**. Paclitaxel plus oxaliplatin for recurrent or metastatic cervical cancer: A New York Cancer Consortium study. *Gynecol Oncol*. 116(3):442-6. 2010. PMID: 19931137. *Clinicaltrials.gov NCT00057863
 - **Einstein MH**, Novetsky AP, Garg M, Hailpern SM, Huang GS, Fields AL, Kalnicki S, Goldberg GL. Survival and Toxicity Differences between 5-day and Weekly Cisplatin Concomitant with External Beam Radiotherapy and High Dose Rate Brachytherapy in Patients with Locally-Advanced Cervical Cancer. *Cancer*. 2007. Jan 1;109(1):48-53. PMID: 17123270
 - **Einstein MH**, Frimer M, Kuo DYS, Reimers LL, Mehta K, Mutyala S, Huang GS, Hou JY, Goldberg GL. Prospective phase II trial of adjuvant pelvic radiation “sandwiched” between combination paclitaxel, carboplatin chemotherapy in women with uterine papillary serous carcinoma. *Gynecol Oncol*. 124: 21-25. 2012. PMID: 22035806. *Clinicaltrials.gov NCT00231868
 - **Einstein MH**, Klobocista M, Hou JY, Lee S, Mutyala S, Mehta K, Reimers LL, Kuo DYS, Huang GS, Goldberg GL. Phase II Trial of Adjuvant Pelvic Radiation “Sandwiched” Between Ifosfamide or Ifosfamide plus Cisplatin in Women with Uterine Carcinosarcoma. *Gynecol Oncol*. 124: 26-30. 2012. PMID:22055846 *Clinicaltrials.gov NCT0023184
3. I have been active in translating clinical trial and translational data into clinical practices regarding cervical cancer prevention including being a Member of the Steering Committee for the American Society for Colposcopy and Cervical Pathology (ASCCP) Cervical Screening and Management Guidelines. This organization produces most of the US cervical cancer screening recommendations, including the most recent cervical cancer screening recommendations and abnormal testing management guidelines. Studies like the one proposed are critical to clinical guideline development.
 - Saslow D et al. (Einstein MH is one of 86 collaborators). American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin*. 62(3): 147-72. 2012. PMID: 22422631 and *J Low Genit Tract Dis*. 2012 Jul;16(3):175-204. PMID: 22418039
 - **Einstein MH**, Martens MG, Garcia FAR, Mitchell AL, Ferris DG, Mitchell AL, Day SP, Olson MC. Clinical Validation of the Cervista® HPV HR Test and 16/18 Genotyping Tests for Use in Cervical Cancer Screening. *Gynecol Oncol*. 118(2): 116-22. 2010. PMID: 20488510
 - Massad LS, **Einstein MH**, Huh WK, Katki HA, Kinney WK, Schiffman M, Solomon D, Wentzensen N, Lawson HW. Updated Guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. *Obstetrics & Gynecology*. 121(4): 829-46. 2013. PMID: 23635684.

- Huh WK, Ault KA, Chelmow D, Davey DD, Goulart RA, Garcia FA, Kinney WK, Massad LS, Mayeaux EJ, Saslow D, Schiffman M, Wentzensen N, Lawson HW, **Einstein MH**. Use of Primary High Risk Human Papillomavirus Testing for Cervical Cancer Screening: Interim Clinical Guidance. *Gynecologic Oncology*. 136(2):178-82, 2015. PMID: 25579107, and *Journal of Lower Genital Tract Disease*. 19(2):91-6, 2015. PMID:25574659
4. As a consultant to the World Health Organization (WHO), I have helped developed their modules on the immunologic basis of HPV vaccines, and harmonizing with current cervical cancer screening for heterogeneous populations across the world. I am currently updating the module.
- **Einstein, MH**. Immunological Basis of Human Papillomavirus Vaccines. Immunological Basis for Immunization Series. World Health Organization. Geneva, Switzerland. 2011.

Complete List of Published Work in MyBibliography:

<https://www.ncbi.nlm.nih.gov/myncbi/1Zgeefna7MSQZ/bibliography/public/>