

## CURRICULUM VITAE

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**Name:** Steven J. Skates

**Education:**

1979 B.Sc. University of Western Australia, Perth, Australia (Mathematics)  
 1987 Ph.D. University of Chicago, Chicago, IL (Statistics)

**Academic Appointments:**

1986 – 1988 Research Fellow in Medicine, Harvard Medical School  
 1988 – 1991 Instructor in Medicine (Biostatistics), Harvard Medical School  
 1991 – 2008 Assistant Professor of Medicine (Biostatistics), Harvard Medical School  
 2008 – Associate Professor of Medicine (Biostatistics), Harvard Medical School

**Committee Memberships:**

1994 Task Force on Clinical Research, Infrastructure Subcommittee, Massachusetts General Hospital  
 1998 – 2001 Subcommittee for Review of Research Proposals (SRRP), Massachusetts General Hospital  
 2001 – 2021 Trial Management Committee, United Kingdom Collaborative Trial of Ovarian Cancer Screening  
 2002 NCI Special Emphasis Panel, Cancer Prognosis & Prediction: Phased Application Awards and SBIR/STTR Initiative  
 2007 AACR-FDA-NCI Cancer Biomarkers Collaborative Committee: To develop recommendations to the FDA on cancer biomarkers in clinical trials.  
 2008 American Cancer Society Panel on Ovarian Symptoms Management. To develop consensus recommendations for standards of care for diagnostic work-up of women with pelvic symptoms.  
 2009 Scientific and Medical Advisory Committee, Ovarian Cancer National Alliance (OCNA). To advise OCNA on all aspects of early detection of ovarian cancer research.  
 2009 – 2013 Member, NIAID Clinical Proteomics Center Scientific Working Group  
 2009 – 2010 Member, Protect Your Lungs Scientific Advisory Board  
 2010 Member, Scientific Advisory Board for NCI Alliance of Glycobiologists for Detection of Cancer and Cancer Risk  
 2010 – 2013 Member, Ayers Institute for Pre-cancer Detection, Vanderbilt University, Scientific Advisory Board  
 2010 – 2013 Member, NCI Biospecimen Research Network Scientific Steering Committee  
 2011 – present Member, LUNgevity Foundation, Scientific Advisory Board  
 2014 Ad-hoc FDA Panel Member, Molecular and Clinical Genetics Panel, FDA's Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), Panel Hearing for two Pre-Marketing Applications (PMA) for Early Detection of Colorectal Cancer, FDA, Silver Spring MD, March 2014  
 2015 – present FDA Panel Member – permanent (4 year term, renewed), Molecular and Clinical Genetics Panel

2015 – present	Consultant to other panels of the Medical Devices Advisory Committee, and to the Center for Devices and Radiological Health
2016	NCI Cancer Biomarkers Study Section (CBSS) (ad hoc member)
2016	NCI Special Emphasis Panel (ad hoc member), ZCA1 SRB-5 (J1)
2016	FDA Microbiology Devices Panel (ad hoc member), meeting for the Application of Procalcitonin to the Evaluation and Management of Suspected Lower Respiratory Tract Infections and Sepsis, Gaithersburg MD, November 2016.
2016	Internal Advisory Board (IAB) Member, Center for Innovation in Early Cancer Detection (IECD), MGH Cancer Center
2017 – 2021	NCI Cancer Biomarkers Study Section (CBSS) (member, 4 year term)
2023 –	American Cancer Society, Guidelines Development Group
2023	FDA, Advisory Committee – provide expert scientific and clinical input regarding the design of multi-cancer detection (MCD) in vitro diagnostic tests as well as study design and approaches to assess probable benefits and risks of MCD screening tests.
2023 –	Co-chair, NCI Early Detection Research Network (EDRN), Breast-Gyn Collaborative Working Group

#### **Awards and Honors:**

1976	James award (Mathematics)
1976	James award (Chemistry)
1979	H.C. Levy award (Mathematics)
1986	Mellon Fellowship for Quantitative Methods in Medicine
2006	Raine Visiting Professorship, University of Western Australia
2011	MGH Gynecologic Cancer Research Program Award
2019	Jonathan Kraft Award for Innovation in Cancer Research (joint with Lecia Sequist, Willhelm Haas)

#### **Research**

My research aims to discover new methods for the early detection of cancer through:

1. Biomarker discovery, verification, and validation with proximal and longitudinal biospecimens.
2. Longitudinal algorithms to combine biomarker information over multiple time points.
3. Conducting early detection screening trials with longitudinal multiple biomarker algorithms.

#### **Funded Research:**

1992 – 1992	HMS Milton Award, "Computer intensive searches for CA-125 screening strategies to maximally reduce mortality from ovarian cancer."
1992 – 1997	NCI, "One step optimization of screening for ovarian cancer"
1993 – 1993	Centocor, Inc., "Re-analysis of stored serum bank from Stockholm ovarian cancer screening study for longitudinal CA125II levels."
1994 – 1997	Whitaker Foundation, "Robust optimal control of long-term oral anticoagulation therapy."
1998 – 2003	NCI, Finkelstein (PI), "Statistical Coordinating Center for the Cancer Genetics Network"
2000 – 2010	Medical Research Council UK, Jacobs (PI), "UK Collaborative Trial of Ovarian Cancer Screening"
2000 – 2010	NCI, Cramer (PI), "Proteomic/Epidemiologic Paths to Ovarian Cancer Screening"
2000 – 2009	NCI, Bast (PI), "Specialized Program of Research Excellence in Ovarian Cancer (SPORE)"

- 2001 – 2005 NCI, “CGN Ovarian Cancer Screening Pilot Trial in High-Risk Women”
- 2003 – 2008 NCI, Atkins (PI), “Specialized Program of Research Excellence in Renal Cell Carcinoma (SPORE)”
- 2004 – 2009 NCI, DF/HCC Ovarian SPORE, Project 3: Biomarkers of Occult Ovarian Cancer from High Risk Women Undergoing Prophylactic Oophorectomy
- 2005 – 2006 Fujirebio Diagnostics Inc, PI, “Identification of Ovarian Cancer Biomarkers using the ROCA Algorithm”
- 2006 – 2011 NCI, Carr (PI) “Clinical Proteomics Technology Assessment for Cancer”
- 2009 – 2011 NCI, Paulovich (PI), A Comprehensive Pilot Project to Establish Feasibility of a Human Proteome Detection and Quantitation (hPDQ) project
- 2010 – 2015 NCI, Bast (PI), Early Detection of Epithelial Ovarian Cancer (SPORE)
- 2010 – 2015 NCI, Proteomic, genetic & longitudinal pathways to ovarian cancer biomarker discovery
- 2010 – 2015 NCI, LaBaer (PI), Biomarker detection using NAPPA tumor antigen arrays
- 2011 – 2012 MGH Gynecologic Cancer Research Program RFA Award
- 2011 – 2015 NCI, Collaborative Project on Ovarian Cancer Biomarker Validation
- 2011 – 2016 Cancer Research UK, Jacobs (PI), Risk Stratification, Early Detection and Diagnosis of Ovarian Cancer
- 2012 – 2016 NCI, Carr (PI), Proteo-genomic Discovery, Prioritization, and Verification of Cancer Biomarkers
- 2016 – 2023 NCI, Proteomic, genomic and longitudinal pathways to ovarian cancer biomarker discovery
- 2016 – 2018 Garfield Foundation, Powell (PI), Use of multiple biomarkers with the risk of ovarian cancer algorithm (ROCA) for early detection of ovarian cancer in female carriers of BRCA 1 and BRCA 2 mutations: A Kaiser Permanente Study
- 2016 – 2020 NCI, Bast (PI), MD Anderson Cancer Center EDN- CVC for Early Detection of Ovarian Cancer
- 2016 – 2021 NCI, Paulovich (PI), A unique approach combining avatar mice and targeted mass spectrometry to identify blood biomarkers for early detection of breast cancer.
- 2017 – 2020 UK NIHR, Menon (PI), Long term impact of screening on ovarian cancer mortality in the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS)
- 2017 – 2021 NCI, Paulovich, Birrer (MPI), Proteogenomic studies aimed at understanding ovarian tumor responses to agents targeting the DNA damage response and translating this knowledge into clinical benefit
- 2017 – 2022 NCI, Patel, Skates (MPI), Lung Cancer Screening via Ultrasensitive and Cost-efficient Analysis of Tumor DNA Signatures in Blood
- 2020 – 2025 NCI, D’Andrea, Castro, Matulonis (MPI), DF/HCC Ovarian Cancer SPORE
- 2021 – 2026 NCI, Proteomic Analyses of Serial Prediagnostic PLCO Serum in Cases and Controls to Identify Early Detection Ovarian Cancer Biomarkers Rising in a Substantial Fraction of Cases and Stable in Most Controls
- 2021 – 2026 NCI, Patel, Skates (MPI), Genome-wide methylation and proteomic analysis of uterine lavage and cervical swab for early detection of ovarian cancer

**Bibliography:****Original Articles**

1. Keast D, Rowe P, Sanfelieu L, Shannahan J, Bowra B, **Skates SJ**, Stapley EO, Woodruff HB, Use of a computer to group actinomycetes for studies on the ecology of soil microorganisms. *Appl Environ Microbiol.* 1984; 48(4):791-6.
2. Reid WH; **Skates SJ**. On The Asymptotic Approximation of Integrals. *SIAM J Appl Math.* 1986 46(3), 351-358.
3. Willett CG, Tepper JE, **Skates SJ**, Wood WC, Orlow EC, Duttonhaver JR. Adjuvant postoperative radiation therapy for colonic carcinoma. *Ann Surg.* 1987; 206(6):694-8.
4. Willett CG, Linggood RM, Leong JC, Miketic LM, Stracher MA, **Skates SJ**, Kushner DC. Stage IA to IIB mediastinal Hodgkin's disease: three-dimensional volumetric assessment of response to treatment. *J Clin Oncol.* 1988 May;6(5):819-24. PMID:3367187
5. Willett CG, Stracher MA, Linggood RM, Miketic LM, Leong JC, **Skates SJ**, Kushner DC, Jacobson JO. Three-dimensional volumetric assessment of response to treatment: stage I and II diffuse large cell lymphoma of the mediastinum. *Radiation Oncol.* 1988 Jul;12(3):193-8. PMID:3175046
6. Okunieff P, Rummeny E, Vaupel P, **Skates SJ**, Willett C, Neuringer LJ, Suit HD. Effects of pentobarbital anesthesia on the energy metabolism of murine tumors studied by in vivo <sup>31</sup>P nuclear magnetic resonance spectroscopy. *Radiat Res.* 1988 Aug;115(2):361-72. PMID:3406373
7. Austin-Seymour M, Munzenrider J, Goitein M, Verhey L, Urie M, Gentry R, Birnbaum S, Ruotolo D, McManus P, **Skates SJ**, et al. Fractionated proton radiation therapy of chordoma and low-grade chondrosarcoma of the base of the skull. *J Neurosurg.* 1989 Jan;70(1):13-7. PMID:2535872
8. Lauk S, Zietman A, **Skates SJ**, Fabian R, Suit HD. Comparative morphometric study of tumor vasculature in human squamous cell carcinomas and their xenotransplants in athymic nude mice. *Cancer Res.* 1989 Aug 15;49(16):4557-61. PMID:2743340
9. Tolentino FI, Cajita VN, Gancayco T, **Skates SJ**. Vitreous hemorrhage after closed vitrectomy for proliferative diabetic retinopathy. *Ophthalmology.* 1989 Oct;96(10):1495-500. PMID:2587044
10. Lauk S, **Skates SJ**, Goodman M, Suit HD. A morphometric study of the vascularity of oral squamous cell carcinomas and its relation to outcome of radiation therapy. *Eur J Cancer Clin Oncol.* 1989; 25(10):1431-40.
11. Thor AD, Schwartz LH, Koerner FC, Edgerton SM, **Skates SJ**, Yin S, McKenzie SJ, Panicali DL, Marks PJ, Fingert HJ. Analysis of c-erbB-2 expression in breast carcinomas with clinical follow-up. *Cancer Res.* 1989; 49(24 Pt 1):7147-52.
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13. **Skates SJ**, Singer DE. Quantifying the potential benefit of a CA-125 screening for ovarian cancer. *J Clin Epidemiol* 1991; 44(4):365-380.
14. Rigotti NA, Neer RM, **Skates SJ**, Herzog DB, Nussbaum SR. The clinical course of osteoporosis in anorexia nervosa: a longitudinal study of cortical bone mass. *JAMA* 1991; 265:1133-1138.
15. Niles JL, Pan GL, Collins AB, Shannon T, **Skates SJ**, Fienberg R, Arnaout MA, McCluskey RT. Antigen-specific radioimmunoassays for anti-neutrophil cytoplasmic antibodies in the diagnosis of rapidly progressive glomerulonephritis. *J Am Soc Nephrol* 1991; 2(1):27-36.
16. Eagle KA, Mulley AG, Field TS, **Skates SJ**, Bero G, Clark CE, Sexton JO, Reder VA, Berrigan G, Procaccini J. Variation in intensive care unit practices in two community hospitals. *Med Care.* 1991 Dec;29(12):1237-45. PMID:1745081
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20. Atlas SJ, Singer DE, **Skates SJ**. Changing blood use in the AIDS era: The case of elective hip surgery. *Transfusion* 1994; 34:286-391.
21. Pardo FS, Aronen HJ, Kennedy D, **Skates SJ**, Paiva K, Okunieff P, Schmidt EV, Hochberg FH, Harsh GR, Fishman AJ, Linggood RM, Rosen BR. Functional cerebral imaging in the evaluation and radiotherapeutic treatment planning of patients with malignant glioma. *Int J Rad Oncol Biol Phys* 1994.
22. **Skates SJ**, Xu F-J, Yu Y-H, Sjovall K, Einhorn N, Chang Y, Bast RC, Knapp RC. Toward an optimal algorithm for ovarian cancer screening with longitudinal tumor markers. *Cancer* 1995; 76:2004-2010.
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38. Hylek EM; Chang YC; **Skates SJ**; Hughes RA; Singer DE. Prospective study of the outcomes of ambulatory patients with excessive warfarin anticoagulation. *Arch Intern Med*. 2000, 160(11), 1612-17.
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**Thesis**

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