

**Harvard Medical School  
Curriculum Vitae**

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**Place of Birth:** Montreal, Quebec, Canada

**Education**

1996	MD, CM	Medicine	McGill University Faculty of Medicine, Montreal, Quebec, Canada
2002	MPH	Public Health	Harvard School of Public Health (HSPH), Boston, MA

**Postdoctoral Training**

7/1996 – 6/1999	Intern and Resident	Internal Medicine	Royal Victoria Hospital, McGill University Health Center, Montreal, Canada
7/1999 – 6/2002	Clinical Fellow	Hematology and Medical Oncology	Dana-Farber Cancer Institute (DFCI)/Partners CancerCare, Boston, MA
7/1999 – 6/2002	Clinical Fellow	Medicine	Harvard Medical School (HMS), Boston MA
7/1999 – 6/2002	Clinical Fellow	Medicine	Brigham and Women’s Hospital (BWH), Boston, MA

**Faculty Academic Appointments**

7/2002-6/2006	Instructor	Medicine	HMS
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7/2006-5/2011	Assistant Professor	Medicine	HMS
6/2011-	Associate Professor	Medicine	HMS

**Appointments at Hospitals/Affiliated Institutions**

7/2009-6/2012	Physician	Medical Oncology	DFCI
7/2012-9/2017	Senior Physician	Medical Oncology	DFCI
9/2017-	Institute Physician	Medical Oncology	DFCI
7/2002-	Associate Physician	Medicine (Oncology)	BWH
7/2009-	Member	Leukemia and Cancer Immunology	Dana-Farber/Harvard Cancer Center (DF/HCC), Boston, MA
8/2009-	Affiliate Faculty	Cancer Program	Harvard Stem Cell Institute (HSCI), Cambridge, MA

**Major Administrative Leadership Positions**

2010 -	Medical Director, Stem Cell Transplantation Survivorship Clinic	DFCI
2015 -	Director, Advanced BMT Fellowship Program	DFCI
2017 -	Director, Clinical Research	Division of Stem Cell Transplantation, DFCI
2019-	Medical Director, Stem Cell Transplantation	DFCI

**Committee Service**

**Local**

2003-2009	Human Subjects Committee, Office for the Protection of Research Subjects	DFCI
2004-2005	Longitudinal Medical Record Working Committee	DFCI
2011–2013	Clinical Systems and Technology Advisory Group	BWH

2011-2014	Revenue Integrity Workgroup	DFCI
2013-2015	Clinical Sciences Coordinating Committee	DFCI
2014-2015	EPIC BMT, Beacon Workgroups	DFCI
2018-	Executive Committee for Clinical Research	DFCI
2019-	Clinical Trial Advisory Board	DFCI
2020-	Chair, BMT Faculty Search Committee	DFCI

### **National**

2004	National Institutes of Health (NIH) Consensus Group on Chronic GVHD; Supportive Care Workgroup	National Cancer Institute (NCI), Bethesda, MD
2014	Chair, Clinical Trials Working Group; NIH Consensus Group on Chronic GVHD	NCI
2019-	3 <sup>rd</sup> NIH Consensus Group on Chronic GVHD; Co-Chair, Diagnostic and Pre-Emptive Therapy Workgroup	NCI

### **International**

2002-	GVHD and Acute Leukemia Working Committees	Center for International Blood and Marrow Transplantation Research (CIBMTR), Milwaukee, WI
2008-2010	Advisory Committee	CIBMTR
2011-2015	Co-Chair, GVHD Working Committee	CIBMTR
2012-2015	Clinical Trials Advisory Committee	CIBMTR
2014	Annual Program Committee	Tandem CIBMTR / ASBMT Annual Meeting
2016	Annual Program Co-Chair	Tandem CIBMTR / ASBMT Annual Meeting
2016-2017	Member, Nominating Committee	CIBMTR
2018-	Chair, Nominating Committee	CIBMTR

## **Professional Societies**

1999	Royal College of Physicians of Canada	
1999	American Medical Association (AMA)	
1999	American Society of Clinical Oncology (ASCO)	
2002	American Society of Hematology (ASH) 2019	Member, Abstract Review Committee
2002	American Society for Transplantation and Cellular Therapy (ASTCT) [Formerly American Society of Blood and Marrow Transplantation] (ASBMT) 2008-2010 2008-2010 2009-2012 2009-2013 2009-2013 2012-2014 2015- 2019-	Foreign Medical Graduate Committee Chair, Task Force on Generic Drugs on Stem Cell Transplantation Task Force on Clinical Practice Guidelines Chair, Committee on Young Clinicians and Investigators Director, Clinical/Laboratory Care Chair, Professional Affairs Council Treasurer Member, Abstract Review Committee
2014-2016	International Society for Stem Cell Research (ISSCR) Task Force on Patient Relations	

## **Grant Review Activities**

2005-2007	ASH Study Section	American Society of Hematology, Washington, DC
2005	Cooperative Group Trials Review ( <i>Ad Hoc</i> )	Cancer Therapeutics and Evaluation Program, Bethesda, MD
2009-	Amy Strelzer Manasevit Award	National Marrow Donor Program, Minneapolis, MN
2011	Transplantation Study Section ( <i>Ad hoc</i> )	National Heart, Lung, Blood Institute Bethesda, MD

2013-	ASBMT Clinical Scholars Summer Grants	American Society of Blood and Marrow Transplantation, Chicago, IL
2017	Orphan Drug Product Grants	Food and Drug Administration, Bethesda MD
2018-	Grant Review Committee Permanent Member	California Institute for Regenerative Medicine

## **Editorial Activities**

### ***Ad hoc* Reviewer**

*American Journal of Hematology*  
*Biology of Blood and Marrow Transplantation*  
*Blood*  
*Blood Advances*  
*Bone Marrow Transplantation*  
*British Journal of Hematology*  
*Haematologica*  
*Journal of Clinical Oncology*  
*Leukemia and Lymphoma*

### **Other Editorial Roles**

2005-	Member, Editorial Board	<i>Biology of Blood and Marrow Transplantation</i>
2007-	Member, Editorial Board	<i>American Journal of Hematology</i>
2011-2014	Member, Editorial Board	<i>Bone Marrow Transplantation</i>
2013-2016	Member, Editorial Board	<i>Journal of Clinical Oncology</i>

## **Honors and Prizes**

1996	Boeringher Ingelheim Prize in Internal Medicine	McGill University Faculty of Medicine	Clinical Achievement
1997	Merck Frosst Resident Research Award	McGill University Faculty of Medicine	Research Achievement
1998	Ted Giles Prize	Royal College of Physicians and Surgeons of Canada	Research Achievement
2002	Partners in Excellence Award	DFCI	Clinical Achievement

2004, 2005	Dunkin' Donuts Rising Stars Award	DFCI	Research Achievement
2010	Fund-A-Grant Honoree	Gateway for Cancer Research	Research Achievement
2012	Distinguished Service Award	Blood and Marrow Transplant Clinical Trials Network	Clinical Service
2013	George Canellos Award	DFCI	Clinical Investigation and Patient Care

## **Report of Funded and Unfunded Projects**

### **Funding Information**

#### **Past**

2001-2002	Decision Analysis of Allogeneic BMT for MDS PI Friends of the Dana-Farber This grant was to support the preliminary costs of a large patient-data decision analysis examining the optimal timing of transplantation in myelodysplastic disorders.
2001-2002	CALGB Fellowship Award Cancer and Leukemia Group B PI This educational grant funded Master of Public Health studies
2001-2003	Physician Scientist Award Leukemia Research Foundation of America PI This grant was to support a large patient-data decision analysis examining the optimal timing of transplantation in myelodysplastic disorders.
2002-2004	Blood vs. Bone Marrow Transplant NHLBI R01 HL071650-01 Co-PI (PI: Benjamin Djulbegovic, MD, PhD) This grant supported a large individual patient meta-analysis comparing peripheral blood stem cells to bone marrow for use in matched, sibling allogeneic hematopoietic stem cell transplantation.
2004-2006	Sirolimus in Allogeneic Transplant Dunkin' Donuts Rising Stars PI This grant supported preliminary institutional phase I-II studies of the novel immunosuppressant sirolimus in allogeneic hematopoietic stem cell transplantation.
2006-2010	Novel Approaches for Prevention and Treatment of Chronic GHVD Gateway to Cancer Research P-06-005

PI

This grant funds two ongoing clinical trials of novel therapeutics (rituximab and alemtuzumab) in chronic GVHD prevention/treatment.

- 2009-2011 Specialized Center for Cell Based Therapy  
NHLBI U54 HL081030-04  
Clinical Trial PI (PI: Henry Kronenberg, MD)  
The primary objective of this trial was to determine the safety of ex-vivo 16,16 dimethyl-prostaglandin E<sub>2</sub>-expanded umbilical cord blood units when used for transplantation in a reduced intensity, sequential umbilical cord blood transplantation model.
- 2007-2012 Improving Outcomes Assessment in Chronic GVHD  
NCI U01 CA118953-01A1  
Site PI (Overall PI: Stephanie J. Lee, MD, MPH)  
The goal of this grant was to assemble a longitudinal cohort of patients with chronic GVHD and to prospectively apply the NIH Consensus Criteria for the Diagnosis and Staging of Chronic GVHD to this cohort. In addition, correlations with long-term outcomes, including overall survival will be made.
- 2004-2015 Mechanisms of GVHD  
NHLBI P01 HL070149-01A1  
Investigator (PI: Joseph H. Antin, MD)  
The major goals of this study were to define new treatment and prophylaxis paradigms for GVHD.
- 2009-2016 Immune Mediated Disorders After Allogeneic HCT  
U54 CA163438  
Site PI (Overall PI: Stephanie J. Lee, MD, MPH)  
The major goals of this grant were 1) To establish a biorepository of cellular and serum specimens from patients after allogeneic hematopoietic stem cell transplantation for chronic GVHD biomarkers discovery; 2) To perform multi-center clinical trials in chronic GVHD as part of the NIH Rare Disease Clinical Network.
- 2013-2018 A Framework for Explanatory Clinical Trials for the Treatment of Acute Graft-vs-Host Disease  
DFCI Medical Oncology Grant  
PI  
The goals of this project were to test, in rapid succession, multiple novel agents for the treatment of GVHD, and to move these compounds into larger phase II trials.
- 2013-2018 Effects of PGE<sub>2</sub> on reconstitution of hematopoiesis and immunity after UCBT  
NHLBI R01 HL118774-01  
Co-PI (Co-PI: Vassiliki A. Boussiotis, MD, PhD)  
The goals of this project were to test the hypothesis that prostaglandin E<sub>2</sub> pretreatment can improve outcomes in umbilical cord blood transplantation by accelerating donor cell immune reconstitution, with a focus on T cell and dendritic cell functions.
- 2013-2018 Improving Outcomes Assessment in Chronic Graft vs. Host Disease  
NIH/NCI R01 CA118953

Site PI (Overall PI: Stephanie J. Lee, MD, MPH)

The major goals of this project were to develop and validate the CGVHD-AI as a measure of treatment response, to develop and validate the CGVHD-SS predictive of failure free survival, and to determine if the CGVHD-AI and CGVHD-SS predict disability free survival.

## Current

- 2019-2024 Long-Term Oral Health Outcomes in the Chronic GVHD Consortium  
NIH/National Institute of Dental and Craniofacial Research (NIDCR) R01 DE028336-01A1  
Investigator (PI: Nathaniel Treister)  
The major goals of this project are to determine the extent of tooth loss in AlloHCT recipients and explore its association with oral cGVHD, and to evaluate the association between recalcitrant oral cGVHD and oral-health related quality of life. Subjects are to be recruited from our ongoing Chronic GVHD Consortium Cohort Study.
- 2015-2020 Mechanisms, Prevention and Treatment of Chronic Graft-vs.-Host Disease  
NIH/NCI P01 CA142106  
Overall PI, Project 1 PI, Core A PI (\$8,207,246)  
The major goal of this program study is to identify optimal strategies for the application of B cell-directed therapies for the treatment and prevention of cGVHD. In this collaborative effort, we incorporate novel multi-center clinical trials, preclinical models of cGVHD to identify more effective B cell targeting strategies for future clinical studies, and detailed analysis of patients receiving novel therapies. Project 1 is dedicated to clinical trials of anti-B cell therapy that address the unmet need during three phases of cGVHD: pre-clinical presentation, initial therapy and late stage disease. Project 2 is dedicated to the identification and testing of new drug and peptide therapies of cGVHD in a robust mouse model of cGVHD associated with fibrosis. Project 3 is dedicated to understanding the immunologic effects of B cell-directed therapies and potential mechanisms by which these new treatments alter B cell function *in vivo*.
- 2015-2020 Selection of Allogeneic Hematopoietic Cell Donor Based on KIR and HLA Genotypes  
NIH/National Heart, Blood and Lung Institute (NHBLI) R01 HL129472  
Site PI (\$2,427) (Overall PI: Katharine C. Hsu, MD, PhD)  
The aim of this study is to demonstrate in a prospective multicenter clinical trial for AML patients requiring an allogeneic HCT from an unrelated donor that (1) KIR/HLA combinations can be used to identify and select KIR-advantageous donors, and (2) patients with KIR-advantageous donors will have less relapse and higher survival. Correlative laboratory studies using fluorescence and mass cytometry will demonstrate that donor-derived NK cells exhibit higher NK activity and less inhibition in response to leukemia target cells when their KIR and HLA genotypes imply advantage(s). Combined, these studies have the potential to transform current donor selection practices and reduce the risk of leukemia relapse in patients.
- 2020-2025 Improving Outcomes Assessment in Chronic GVHD  
NIH/NCI R01 CA118953  
Site PI (\$6,154 plus patient costs) (PI: Stephanie J. Lee, MD, MPH)



The primary aim of this project is to identify biologically defined subgroups among chronic GVHD patients, and to understand their association with survival, non-relapse mortality, time to next systemic treatment/duration of treatment, and QOL.

### **Unfunded Current Projects**

- 2012- A Multicenter Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High-Risk Myelodysplastic Syndrome  
I am the national Co-PI of this study designed to test the hypothesis that allogeneic stem cell transplantation provides a survival benefit for patients above the age of 50. This study is being conducted by the Blood and Marrow Transplant Clinical Trials Network, in response to a request from the Centers for Medicare and Medicaid Services.
- 2019-2020 Telomeropathy and Stem Cell Transplantation  
DFCI Medical Oncology Award  
Investigator (PI: R. Coleman Lindsley)  
The goals of the project are to determine the impact of recipient telomere length on transplant-related morbidity and mortality and to identify genetic determinants of telomere length in patients undergoing transplantation.

### **Report of Local Teaching and Training**

#### **Teaching of Students in Courses**

##### **HMS/HSDM/DMS Courses**

- |           |  |                                       |
|-----------|--|---------------------------------------|
| 2000-2001 | Introduction to Clinical Medicine:<br>Clinical History and Physical<br>Examination Skills<br>2 <sup>nd</sup> year medical students | HMS<br><br>6 hours/week, 4 weeks/year |
| 2001-2005 | Hematologic Pathophysiology - Small<br>Group Tutor<br>2 <sup>nd</sup> year medical students  | HMS<br><br>6 hours/week, 4 weeks/year |

##### **Other Harvard University Courses**

- |       |   |   |
|-------|---|---|
| 2002  | Epidemiology Seminar Series<br>MPH Candidates   | HSPH<br>1-hour lecture  |
| 2019- | Harvard Stem Cell and Regenerative<br>Biology Course 167 – Stem Cell Biology<br>– Principles of BMT<br>Undergraduate students | Faculty of Arts of Sciences, Harvard<br>University, Cambridge, MA<br><br>1-hour lecture |

### **Clinical Supervisory and Training Responsibilities**

2002-	Inpatient Attending, Medical Oncology Medical students, residents, fellow	BWH
2002-	Ambulatory Clinic Preceptor, Stem Cell Transplantation Clinic Hematology/Oncology fellows	DFCI

### **Laboratory and Other Research Supervisory and Training Responsibilities**

2012-	Supervision of Advanced BMT fellow and 1 <sup>st</sup> year Hematology/Oncology fellow	1:1 supervision 1-3 hrs per wk and 2 hrs per wk, respectively
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### **Formally Mentored Harvard Medical, Dental and Graduate Students**

2012	Arwa Farag, HMS Class of 2012 I was a member of the DMSc thesis committee for Dr. Farag. Thesis: T Cell Reconstitution after Allogeneic Stem Cell Transplantation in Patients with Graft- versus-Host Disease
2015	Ali Aboalela, HMS Class of 2015 I was a member of the DMSc thesis committee thesis committee for Dr. Aboalela. Thesis: Immune Reconstitution of B Cells Following Allogeneic Hematopoietic Cell Transplantation
2019-	Roxanne Bavarian, HMS Class of 2019 I was a member of the DMSc thesis committee for Dr. Bavarian. Thesis: NAD Supplementation for Oral Mucositis

### **Other Mentored Trainees and Faculty**

2012-2014	Sarah Nikiforow, MD, PhD, Medical Director Cell Manipulation and Gene Transfer Laboratory, DFCI, Assistant Professor of Medicine, HMS <i>Career stage:</i> Fellow; junior faculty // <i>Mentoring role:</i> Co-Mentor (with Jerome Ritz) <i>Accomplishments:</i> 2 published mentored manuscripts; Karl Blume Editorial Prize – Biology and Blood Marrow Transplant; New Investigator Award, American Society of Blood and Marrow Transplantation; ASH Fellow Scholar Award.
2013-2015	Natasha Kekre, MD, Clinician-Scientist, Ottawa General Hospital, Assistant Professor of Medicine, University of Ottawa <i>Career stage:</i> Fellow // <i>Mentoring role:</i> Co-Mentor (with Joseph Antin, MD) <i>Accomplishments:</i> 1 published manuscript, 1 manuscript under review.
2016-2019	Mahasweta Gooptu, MD, Physician, Division of Stem Cell Transplantation, DFCI, Instructor in Medicine, HMS <i>Career stage:</i> Fellow, junior faculty // <i>Mentoring role:</i> Mentor <i>Accomplishments:</i> 2 published manuscripts; appointed to faculty 2017.

- 2016- Sherrie Divito, MD, PhD, Physician, Dermatology, BWH, Assistant Professor of Dermatology, HMS  
*Career stage:* Junior faculty // *Mentoring role:* Co-Mentor of K08 grant (with Thomas Kupper)  
*Accomplishments:* None to date; project in process.
- 2017-2018 Clinton Lewis, MD, Physician, Auckland District Health Board, Auckland, New Zealand  
*Career stage:* Advanced Clinical Fellow // *Mentoring role:* Mentor  
*Accomplishments:* 1 published manuscript.
- 2018-2019 Cynthia Hickey, MD, (Currently on LOA)  
*Career stage:* Advanced Stem Cell Transplantation Fellow // *Mentoring role:* Mentor  
*Accomplishments:* ASH Abstract Achievement Award, 2019
- 2019- Roman Shapiro, MD, Advanced Stem Cell Transplantation Fellow, DFCI  
*Career stage:* Fellow // *Mentoring role:* Mentor  
*Accomplishments:* 1 review accepted for publication.

**Formal Teaching of Peers (e.g., CME and other continuing education courses)**

*No presentations below were sponsored by outside entities.*

- 2018 Biology of Bone Marrow Transplantation  
 Cancer Medicine and Hematology Postgraduate Course, Fairmont-Copley Plaza Hotel, Boston, MA
- 2019 Redefining the Indications for Stem Cell Therapy in Hematologic Malignancies  
 Cancer Medicine and Hematology Postgraduate Course, Fairmont-Copley Plaza Hotel, Boston, MA

**Local Invited Presentations**

*No presentations below were sponsored by outside entities.*

- 2001 Peripheral Blood Stem Cells and Bone Marrow in Allogeneic Transplantation: Similarities, Differences and Choices / Invited speaker  
 HMS Bone Marrow Transplant Conference, DFCI, Boston, MA
- 2003 Stem Cell Transplantation for MDS: Who, When, Why, How / Invited speaker  
 HMS Bone Marrow Transplant Conference Dana-Farber Cancer Institute, Boston, MA
- 2003 Sirolimus: A Novel Compound in Allogeneic Stem Cell Transplantation / Invited speaker  
 HMS Bone Marrow Transplant Conference, DFCI, Boston, MA
- 2006 Novel B Cell Therapies in Stem Cell Transplantation / Lymphoma Conference  
 Massachusetts General Hospital (MGH), Boston, MA

- 2007 Sirolimus in Allogeneic Transplantation – Clinical Results / Invited speaker  
Harvard Transplant Immunology Conference, DFCI, Boston, MA
- 2010 Sirolimus in Allogeneic Stem Cell Transplantation / Invited speaker  
Pediatric Transplantation Seminar, DFCI, Boston, MA
- 2012 PGE2 Modulated Umbilical Cord Blood Transplantation / Invited speaker  
Hematologic Neoplasia Seminar, DFCI, Boston, MA
- 2014 Expansion and PGE2 Modulation of Umbilical Cord Blood / Grand Rounds  
Hematology Division, DFCI, Boston, MA
- 2014-2016 Survivorship in Stem Cell Transplantation / Invited speaker  
Leukemia and Lymphoma/Survivorship Conference, DFCI, Boston, MA
- 2016 Transplantation for Myelodysplastic Syndrome – Clinical and Molecular Risk  
Assessment / Invited speaker  
Hematologic Neoplasia Conference, DFCI, Boston, MA
- 2019 B-Cells in Chronic GVHD / Hematology Grand Rounds  
Division of Hematology, BWH, Boston, MA

## **Report of Regional, National and International Invited Teaching and Presentations**

### **Invited Presentations and Courses**

*No presentations below were sponsored by outside entities.*

#### **Regional**

- 1996 Cutaneous Malignant Melanoma Is Associated with an Increased Incidence of Melanoma  
and Colorectal Carcinoma in First Degree Relatives / Invited speaker  
Department of Medicine Faculty Research Seminar, McGill University, Montreal,  
Quebec, Canada
- 2007 Sirolimus in Allogeneic Transplantation / Bone Marrow Transplant Grand Rounds  
Division of Hematology/Oncology, Tufts-New England Medical Center, Boston, MA
- 2010 Umbilical Cord Blood Transplantation – The DFCI Experience / Bone Marrow  
Transplant Grand Rounds  
Division of Hematology, Tufts Medical Center, Boston, MA
- 2014-2016, ASH Highlights Conference / Invited speaker  
2018  
Boston Newton Marriott, Newton, MA
- 2019 Survivorship in Stem Cell Transplant  
Hematology Grand Rounds, University of Massachusetts, Worcester, MA

## National

- 1998 HTLV-1 Associated Adult T Cell Leukemia/Lymphoma from a Newly Identified Endemic Region / Invited speaker  
Royal College of Physicians and Surgeons Annual Meeting, Toronto, Ontario, Canada
- 2004 Medical Decision Making: What Do We Need to Know to Make Tough Choices / Workshop Co-Chair  
ASBMT/IBMTR Tandem Stem Cell Transplant Meeting, Orlando, FL
- 2005 Novel Agents in GVHD Prophylaxis – Sirolimus / Invited speaker  
BMT Pharmacists Conference, Keystone, CO
- 2005 Approach to Transplantation for the Myelodysplastic Syndromes / Invited speaker  
National Marrow Donor Program Meeting, Phoenix, AZ
- 2005 Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndromes: Patient Selection, Prognostic Factors and Optimal Timing / Invited speaker  
American Association of Blood Banks Annual Meeting, Seattle, WA
- 2005 B Cell Therapy for Chronic Graft-vs.-Host Disease / Invited speaker  
American Society of Blood and Marrow Transplantation / Center for International Blood and Marrow Transplantation Research Annual Meeting, Honolulu, HI
- 2005 Approach to the Patient with Chronic GVHD / Invited speaker  
National Marrow Donor Program (Webinar)
- 2007 Sirolimus in Allogeneic Stem Cell Transplantation / Invited speaker  
University of S. Florida Moffitt Cancer Center Transplantation Rounds, Tampa, FL
- 2007 Clinical Trials Methodology, Novel Agents in GVHD and Financial Issues in Trial Design / Invited speaker  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Keystone, CO
- 2008 Clinical Trials Methodology, Novel Agents in GVHD and Financial Issues in Trial Design / Invited speaker  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Park City, UT
- 2008 MDS Treatment Advances: Applying New Data for Decision Making /Invited speaker  
National Marrow Donor Program Webinar
- 2008 Update in Acute and Chronic GVHD / Invited speaker  
National Marrow Donor Program Council Meeting, Minneapolis, MN
- 2008 Sirolimus in Allogeneic Stem Cell Transplantation / Oncology Grand Rounds  
University of Pittsburgh, Pittsburgh, PA

- 2009 Optimizing Transplant Outcomes in Myelodysplastic Disorders / Invited speaker  
Myelodysplastic Syndrome Conference, University of Texas M.D. Anderson Cancer Center, Houston, TX
- 2009 Clinical Trials Methodology, Novel Agents in GVHD and Financial Issues in Trial Design / Invited speaker  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Park City, UT
- 2009 Acute Myeloid Leukemia – Update on Diagnosis, Prognosis and Treatment / Invited speaker  
Association of Physician Assistants in Oncology Annual Meeting, Boston, MA
- 2010 Highlights of ASH – Stem Cell Transplantation / Invited speaker  
ASH Highlights Course, San Antonio, TX
- 2010 Should Methotrexate Plus Calcineurin Inhibitors Be Considered Standard of Care for Prophylaxis of Acute Graft-versus-Host-Disease / Debate?  
American Society of Blood and Marrow Transplantation / Center for International Blood and Marrow Transplantation Research Annual Meeting, Orlando FL
- 2010 Peripheral Blood vs. Bone Marrow: Long Term Complications / Invited speaker  
American Society of Blood and Marrow Transplantation / Center for International Blood and Marrow Transplantation Research Annual Meeting, Orlando FL
- 2010 Graft-vs.-Host Disease – Diagnosis, Staging, Prophylaxis and Treatment / Invited speaker  
American Society of Blood and Marrow Transplantation / Center for International Blood and Marrow Transplantation Research Mid-Level Providers Annual Meeting, Orlando FL
- 2010 Future Prospects for GVHD Prevention and Therapy / Invited speaker  
Mid-South Cancer Symposium, Memphis TN
- 2010 Clinical Trials Methodology, Novel Agents in GVHD and Financial Issues in Trial Design / Invited speaker  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Park City, UT
- 2010 Stem Cell Transplantation for Myelodysplastic Disorder / Invited speaker  
American Society of Hematology Education Session, Orlando FL
- 2011 Long-Term Complications of GVHD Therapy / Invited speaker  
Seattle Stem Cell Transplantation Survivorship Conference, Seattle WA
- 2011 Clinical Trials Methodology, Novel Agents in GVHD and Financial Issues in Trial Design / Invited speaker  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Santa Fe, NM

- 2011 Rituximab for Prevention of Chronic GVHD / Invited speaker  
9<sup>th</sup> International Umbilical Cord Blood Symposium, San Francisco, CA
- 2011 Prostaglandin-Modulated Umbilical Cord Blood Transplantation / Invited speaker  
International Society of Cellular Therapy, Charlottesville, VA
- 2011 Anti-HLA Antibodies in Umbilical Cord Blood Transplantation / Invited speaker  
National Marrow Donor Program Annual Meeting, Minneapolis, MN
- 2012 GVHD Prophylaxis: Lessons Learned / Invited speaker  
ASBMT Annual Meeting, San Diego, CA
- 2012 Umbilical Cord Blood vs. Haploidentical Transplantation / Invited speaker  
ASBMT Nurses Annual Meeting, San Diego, CA
- 2012 Clinical Trials Methodology, Novel Agents in GVHD and Financial Issues in Trial Design / Invited speaker  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Park City, UT
- 2012 Novel Strategies in GVHD Prophylaxis / Invited speaker  
Cowden Family Foundation / Cleveland Clinic GVHD Symposium, Cleveland, OH
- 2013 Highlights of ASH – Myelodysplastic Syndrome / Invited speaker  
Dallas, TX
- 2013 BMT 101 / Invited speaker  
Advanced Practitioners Conference, ASBMT, Salt Lake City, UT
- 2013 Transplantation for Cutaneous T Cell Non-Hodgkin's Lymphoma / Invited speaker  
American Academy of Dermatology, Miami, FL
- 2013 Transplantation for MDS – Who, When, Why? / Oncology Grand Rounds  
Mount Sinai Hospital Oncology Grand Rounds, New York, NY
- 2013 Transplantation for Cutaneous T Cell Non-Hodgkin's Lymphoma / Invited speaker  
Leukemia and Lymphoma Society Conference, Boston, MA
- 2013 PGE2 in Umbilical Cord Blood Transplantation: Regulatory Challenges / Invited speaker  
Society for Clinical Trials Annual Meeting, Boston, MA
- 2013 Decision Analysis in Medical Research / Invited speaker  
Mount Sinai School of Medicine Summer Program in Epidemiology, New York, NY
- 2013 Prostaglandin E2 in Umbilical Cord Blood Transplantation / Invited speaker  
International Society of Stem Cell Research, Boston, MA

- 2014 Conditioning Regimens in Stem Cell Transplantation / Invited speaker  
American Society of Blood and Marrow Transplantation (Clinical Education Conference), Dallas, TX
- 2014 Molecular Prognostic Features in MDS and Transplantation / Invited speaker  
Society of Hematologic Oncology, Houston, TX
- 2014 Transplantation for Cutaneous T Cell Non-Hodgkin's Lymphoma / Invited speaker  
American Academy of Dermatology, Denver, CO
- 2014 Update in PGE2 in Cord Blood Transplantation / Invited speaker  
Cord Blood Symposium, San Francisco, CA
- 2014 Update in Cord and Haploidentical Transplantation / Invited speaker  
Physician-Assistants of the American Society of Blood and Marrow Transplantation Regional Conference, Boston, MA
- 2014 Transplantation for the Myelodysplastic Disorders and Aplastic Anemia / Invited speaker  
American Society of Hematology Annual Meeting, San Francisco, CA
- 2015 Update in Cord and Haploidentical Transplantation / Invited speaker  
American Society of Blood and Marrow Transplantation (Clinical Education Conference), San Diego, CA
- 2015 B Cell Depletion in the Treatment of Chronic GVHD / Invited speaker  
American Society of Blood and Marrow Transplantation Annual Meeting, San Diego, CA
- 2015 Allogeneic Stem Cell Transplantation for Cutaneous T Cell Lymphoma / Invited speaker  
Inova Health Center, Fairfax, VA
- 2016 Clinical Trial Design in GVHD: Budgeting for Clinical Trials / Invited Faculty, Annual  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Park City, UT
- 2017 BMT 101 / Invited speaker  
Clinical Education Conference, American Society of Blood and Marrow Transplantation Annual Meeting, Orlando, FL
- 2017 Clinical Trial Design in GVHD: Budgeting for Clinical Trials / Invited Faculty, Annual  
American Society of Blood and Marrow Transplantation Clinical Research Training Course, Ballantyne, NC
- 2017 Aiming for Cure: The Role of BMT in Treating Adults with Treatment-Related MDS/AML / Invited speaker  
Society of Hematologic Oncology, Houston, TX



- 2017      Should Molecular Genetics Guide the Decision for Allogeneic Transplant in MDS? /  
Invited speaker  
Cleveland Clinic/Aplastic Anemia Foundation Education Seminar, American Society  
of Hematology Annual Meeting, Atlanta, GA
- 2018      B-Cells in GVHD / Invited speaker  
Hematology Grand Rounds, Moffitt Cancer Center, Tampa, FL
- 2018      Advancing Care for Patients with GvHD: Making Sense of Recent Approvals and  
Late-Stage Compounds / Invited speaker  
Physicians' Education Resource Program, American Society of Hematology Annual  
Meeting, San Diego, CA
- 2019      The Evolving Treatment Landscape for Patients with GvHD: More Options, More  
Decisions, Better Outcomes / Invited speaker  
American Society of Hematology Annual Meeting, Orlando, FL

### **International**

- 2001      Peripheral Blood Stem Cells and Bone Marrow for Allogeneic Transplantation:  
Similarities, Differences and Choices / Medical Grand Rounds  
McGill University Health Science Center, Montreal, QC, Canada
- 2007      Sirolimus in Allogeneic Stem Cell Transplantation / Invited speaker  
Edinburgh Blood Club, Edinburgh, Scotland
- 2009      Optimizing Transplant Outcomes in Myelodysplastic Disorders / Invited speaker  
Toronto Myelodysplastic Syndromes Symposium, Toronto, Ontario, Canada
- 2009      Novel GVHD Prophylaxis / Invited speaker  
Princess Margaret Stem Cell Transplantation Symposium, Toronto, Ontario, Canada
- 2010      Highlights of ASH – Stem Cell Transplantation / Invited speaker  
ASH Highlights Course, Toronto, Ontario, Canada
- 2010      Highlights of ASH - Acute Lymphoblastic Leukemia / Invited speaker  
Brazilian Society of Hematology ASH Review, Rio de Janeiro, Brazil
- 2010      Umbilical Cord Blood: Preventing Failure, Predicting Success / Invited speaker  
Oncology Grand Rounds, Princess Margaret Hospital, Toronto, Ontario, Canada
- 2011      Optimal Timing of Stem Cell Transplantation in MDS / Invited speaker  
International MDS Foundation Conference, Edinburgh, Scotland
- 2011      Transplantation for the Myelodysplastic Syndromes / Invited speaker  
Hellenic Society of Hematology, Athens, Greece
- 2012      Overview of Immunosuppressants for GVHD Prophylaxis and Treatment / Invited  
speaker

- European Bone Marrow Transplant Society Meeting, Geneva, Switzerland
- 2012 Graft-vs.-Host Disease Prophylaxis – Novel Concepts / Invited speaker  
Spanish Society of Hematology, Salamanca, Spain
- 2013 Patient Selection for Transplantation for MDS / Invited speaker  
International MDS Foundation Conference, Berlin, Germany
- 2013 Transplantation for Myelodysplastic Syndromes / Invited speaker  
Canadian Hematology Conference, Toronto, Ontario, Canada
- 2013 Transplantation for Myelodysplastic Syndromes / Invited speaker  
Japanese Society of Hematology, Hamamatsu, Japan
- 2013 Highlights of ASH – Myelodysplastic Syndrome / Invited speaker  
Toronto, Ontario, Canada
- 2014 Transplantation for Myelodysplastic Syndromes – Who and When? / Invited speaker  
Canadian Conference on the Myelodysplastic Syndromes, Banff, Alberta, Canada
- 2016 Update in Chronic GVHD – New NIH Guidelines / Invited speaker  
Canadian Bone Marrow Transplant Group Meeting, Montreal, Quebec, Canada
- 2016 Improving Transplantation for Myelodysplastic Syndromes / Invited speaker  
Canadian Conference on the Myelodysplastic Syndromes, Quebec City, Quebec, Canada
- 2019 Reducing Toxicity in Stem Cell Transplantation / Invited speaker  
Canadian Conference on the Myelodysplastic Syndromes, Vancouver, British Columbia, Canada
- 2019 Transplant in Myelodysplasia and Myeloproliferative Disorders / Invited speaker  
GATMO Immunotherapy and HSCT Conference, Buenos Aires, Argentina
- 2020 Allogeneic Transplantation in an Aging Population / Invited speaker  
International Conference on Bone Marrow Transplantation, Busan, South Korea

## **Report of Clinical Activities and Innovations**

### **Current Licensure and Certification**

- 1996-1999 Resident License, Province of Quebec, Canada
- 1999- Massachusetts Medical License
- 1999- Fellow of the Royal College of Physicians of Canada – Internal Medicine
- 1999-2009 American Board of Internal Medicine - Internal Medicine
- 2002-2012 Fellow of the Royal College of Physicians of Canada – Medical Oncology
- 2002-2012 American Board of Internal Medicine – Medical Oncology Certificate
- 2002- American Board of Internal Medicine – Hematology Certificate

## **Practice Activities**

2002-	Ambulatory Care	Stem Cell Transplantation, DFCI	4 Half-day sessions/week
2002-	Inpatient Care	Stem Cell Transplantation, BWH	6 Weeks/Year
2010-	Ambulatory Care	Cutaneous Oncology, Stem Cell Transplantation, DFCI	1 Half-day session/month
2010-	Ambulatory Care	BMT Survivorship Clinic, DFCI	1 Half-day session/month

## **Clinical Innovations**

Myelodysplastic Syndrome (1999-)

I remain dedicated to understanding the optimal timing of transplantation for this variable group of hematologic disorders. The role of transplantation has become more complicated with the approval of non-transplant therapies to treat this disorder. I currently am leading the national trial to demonstrate superiority of allogeneic stem cell transplantation in comparison to non-transplant therapies. This trial will include outcome measures such as cost-effectiveness and quality of life. Additionally, I have been involved in several national efforts to address the Centers for Medicare Services Coverage with Evidence Determination program.

Novel Approaches in Prevention of Acute Graft-vs.-Host Disease (2000-)

Over the past 20 years I have led the development of sirolimus in graft-versus-host disease (GVHD) prophylaxis. As a result of these studies, sirolimus has become a standard of care at the DFCI and nationwide, considered equivalent to the standard of tacrolimus and methotrexate. This drug is now used broadly across multiple transplant scenarios and conditions, including myeloablative and reduced intensity transplantation, umbilical cord blood transplantation and in transplantation with renal insufficiency. Multiple centers, both in North America and Europe use this agent as part of their standard regimens.

B Cells in Chronic GVHD (2011)

B cells may be implicated in the pathophysiology of chronic graft-versus-host disease (GVHD), as evidenced by antibody production against sex-mismatched, Y chromosome-encoded minor HLA antigens in association with chronic GVHD. I designed a phase 1/2 study of anti-B-cell therapy with rituximab in steroid-refractory chronic GVHD. In this study, we concluded that specific anti-B-cell therapy with rituximab may be beneficial for patients with steroid refractory chronic GVHD. This prospective trial has led to the widespread acceptance of this agent as a therapy in steroid-refractory chronic GVHD. Focusing on B cell signaling, I and my team developed a multicenter, open-label clinical trial that evaluated the safety and efficacy of the BTK-inhibitor, ibrutinib, in patients with active chronic GVHD with inadequate response to corticosteroid-containing therapies. Ibrutinib resulted in clinically meaningful responses with acceptable safety in patients with

greater than or equal 1 prior treatment for cGVHD. Based on these results, ibrutinib was approved by the FDA for treatment of adult patients with cGVHD after failure of 1 or more lines of systemic therapy. I continue to lead innovative trials of novel agents in chronic GVHD prevention and therapy, and I am currently leading the only prospective randomized trial designed to evaluate the role of B cell depletion as a preventative strategy for chronic GVHD.

Umbilical Cord Blood Transplantation and Modulation (2005-)

I have been the leader of the umbilical cord blood transplantation program at DFCI since its inception, developing new conditioning and GVHD prevention regimens. I previously led an industry-academic partnership examining the role of pre-transplantation modulation of umbilical cord blood products with the prostaglandin derivative, 16,16 dimethyl prostaglandin E2. Three clinical trials in different settings have been completed and I remain in charge of our cord blood research program at DFCI.

Stem Cell Transplant Survivorship (2010-)

Over the last few years I have assembled a new clinic at the DFCI, focusing on the long-term survivorship needs of stem cell transplantation clinic. The bi-monthly clinic is staffed by subspecialists in oral medicine, dermatology, ophthalmology as well as nutritionists, exercise physiologists and psychosocial providers.

## **Report of Technological and Other Scientific Innovations**

Workload Assessment Tool for Research Protocols (WARP) (2017-)

The tool is a set of formulas and nomograms that can be used to objectively measure and forecast the workload of an individual or multiple clinical trial protocols. This system of workload management is an improvement over the OPAL scoring system by tailoring the scoring to the individual team using it and implementing the formulas into a comprehensive team dashboard showcasing current workloads, future projections, accrual completion goals, and distribution of effort across research areas. The tool can be used for budgetary projections as well.

## **Report of Education of Patients and Service to the Community**

### **Activities**

*Those presentations below sponsored by outside entities are so noted and the sponsor(s) have been identified.*

- 2005            Young Presidents Organization of Boston / Lecturer  
Decision Making in Stem Cell Transplantation / Invited lecture
- 2009            BMTInfoNet National Survivorship Conference / Planning Committee Member
- 2009            The Role of Public Umbilical Cord Blood Banks / Round Table Discussant  
Massachusetts House of Representative and Senate on the Topic of Umbilical Cord  
Blood Banking (PNC Wealth Management, Sponsor)

- 2010 Leukemia and Lymphoma Society / National Webinar Speaker  
Talk on Stem Cell Transplantation
- 2015 Milken Institute / Faster Cures CMML Advisory Board
- 2015- Aplastic Anemia and Myelodysplastic Syndrome Foundation Patient Education Council  
and Regional Meeting Speaker
- 2017 Prime Oncology National GVHD Education Series Content Development/Speaker
- 2018- Aplastic Anemia and MDS Foundation Education Committee
- 2019 BMTInfoNet Survivorship Planning Committee

### **Report of Scholarship**

**ORCID ID: 0000-0001-8728-4314**

### **Peer-reviewed publications in print or other media**

#### **Research investigations**

1. Tonin P, Moslehi R, Green R, Rosen B, Cole D, Boyd N, **Cutler C**, Margolese R, Carter R, McGillivray B, Ives E, Labrie F, Gilchrist D, Morgan K, Simard J, Narod SA. Linkage analysis of 26 Canadian breast and breast-ovarian cancer families. *Hum Genet.* 1995; 95:545-50.
2. **Cutler C**, Foulkes WD, Brunet J-S, Flanders T, Shibata H, Narod SA. Cutaneous malignant melanoma is associated with an increased incidence of melanoma and colorectal carcinoma in first degree relatives: a case-control study. *Melanoma Res.* 1996; 6:435-40. PMID: 9013481
3. **Cutler C**, Samman Y, Fraser R, Corris P, Zidulka A. Recurrent acute pulmonary toxicity and respiratory failure associated with fludarabine monophosphate. *Can Resp J.* 1997; 4:331-3.
4. **Cutler C**, Giri S, Jeyapalan S, Paniagua D, Viswanathan A, Antin JH. Acute and chronic graft-versus-host disease after allogeneic peripheral blood stem cell and bone marrow transplantation. A meta-analysis. *J Clin Oncol.* 2001; 19:3685-91. PMID: 11504750
5. Wadleigh M, Richardson PG, Zahrieh D, Lee SJ, **Cutler C**, Ho V, Alyea EP, Antin JH, Stone RM, Soiffer RJ, DeAngelo DJ. Prior gemtuzumab ozogamicin exposure significantly increases the risk of veno-occlusive disease in patients who undergo myeloablative allogeneic stem cell transplantation. *Blood.* 2003; 102:1578-82. PMID: 12738663
6. Antin JH, Kim HT, **Cutler C**, Ho VT, Lee SJ, Miklos DB, Hochberg EP, Wu CJ, Alyea EP, Soiffer RJ. Sirolimus, tacrolimus, and low-dose methotrexate for graft-versus-host disease prophylaxis in mismatched related donor or unrelated donor transplantation. *Blood.* 2003; 102:1601-05. PMID: 12738663

7. **Cutler C**, Kim HT, Hochberg E, Ho VT, Alyea E, Lee SJ, Fisher DC, Miklos D, Levin J, Sonis S, Soiffer RJ, Antin JH. Sirolimus and tacrolimus without methotrexate as graft-vs.-host disease prophylaxis after matched, related donor peripheral blood stem cell transplantation. *Biol Blood Marrow Transplant.* 2004;10(5):328-36. PMID: 1511192
8. **Cutler C**, Lee SJ, Greenberg P, Deeg HJ, Pérez WS, Anasetti C, Bolwell BJ, Cairo MS, Gale RP, Klein JP, Lazarus HM, Liesveld JL, McCarthy PL, Milone GA, Rizzo D, Schultz KR, Trigg ME, Keating A, Weisdorf DJ, Antin JH, Horowitz MM. A decision analysis of allogeneic bone marrow transplantation for the myelodysplastic syndromes: delayed transplantation for low risk myelodysplasia is associated with improved outcome. *Blood.* 2004; 104(2):579-85. PMID: 15039286
9. Ho VT, Zahrieh D, Hochberg E, Micale E, Levin J, Reynolds C, Steckel S, **Cutler C**, Fisher DC, Lee SJ, Alyea EP, Ritz J, Soiffer RJ, Antin JH. Safety and efficacy of denileukin diftitox in patients with steroid-refractory acute graft-versus-host disease after allogeneic hematopoietic stem cell transplantation. *Blood.* 2004; 104(4):1224-26. PMID: 15113758
10. Lee SJ, Zahrieh D, Agura E, MacMillan ML, Maziarz RT, McCarthy PL, Ho VT, **Cutler C**, Alyea EP, Antin JH, Soiffer RJ. Effect of up-front daclizumab when combined with steroids for the treatment of acute graft-vs.-host disease: results of a randomized trial. *Blood.* 2004;104(5):1559-64. PMID: 15138163
11. Ho VT, Kim HT, Li S, Hochberg EP, **Cutler C**, Lee SJ, Fisher DC, Milford E, Kao G, Daley H, Levin J, Ng A, Mauch P, Alyea EP, Antin JH, Soiffer RJ. Partial CD8+ T-cell depletion of allogeneic peripheral blood stem cell transplantation is insufficient to prevent graft-versus-host disease. *Bone Marrow Transplant.* 2004; 34(11):987-94. PMID: 15489873
12. Lee SJ, Loberiza FR, Antin JH, Kirkpatrick T, Alyea EP, **Cutler C**, Ho VT, Richardson PG, Schlossman RL, Fisher DC, Logan B, Soiffer RJ. Routine screening for psychosocial distress following hematopoietic stem cell transplantation. *Bone Marrow Transplant.* 2005;35(1):77-83. PMID: 15502851.
13. Alyea EP, Kim HT, Ho V, **Cutler C**, Gribben J, DeAngelo D, Lee SJ, Widanaw S, Ritz J, Stone RM, Antin JH, Soiffer RJ. Comparative outcome of nonmyeloablative and myeloablative allogeneic hematopoietic cell transplantation for patients older than 50 years of age. *Blood.* 2005; 105(4):1810-14. PMID: 15459007
14. Miklos DB, Kim HT, Miller KH, Guo L, Zorn E, Lee SJ, Hochberg EP, Wu CJ, Alyea EP, **Cutler C**, Ho V, Soiffer RJ, Antin JH, Ritz J. Antibody responses to H-Y minor histocompatibility antigens correlate with chronic graft versus host disease and disease remission. *Blood.* 2005; 105:2973-8. PMID: 15613541; PMCID: PMC1350982
15. **Cutler C**, Li S, Kim HT, Laglenne P, Szeto KC, Hoffmeister L, Harrison MJ, Ho V, Alyea E, Lee SJ, Soiffer R, Sonis S, Antin JH. Mucositis after allogeneic hematopoietic stem cell transplantation: a cohort study of methotrexate and non-methotrexate containing GVHD prophylaxis regimens. *Biol Blood Marrow Transplant.* 2005; 11(5):383-8. PMID: 15846292

16. **Cutler C**, Henry NL, Magee C, Li S, Kim HT, Alyea E, Ho V, Lee SJ, Soiffer R, Antin JH. Sirolimus and thrombotic microangiopathy after allogeneic hematopoietic stem cell transplantation. *Biol Blood Marrow Transplant*. 2005; 11(7):551-7. PMID: 15983555
17. Couriel D, Carpenter PA, **Cutler C**, Bolanos-Meade J, Treister NS, Gea-Banacloche J, Shaughnessy P, Hymes S, Kim S, Wayne AS, Chien JW, Neumann J, Mitchell S, Syrjala K, Moravec CK, Abramovitz L, Liebermann J, Berger A, Gerber L, Schubert M, Filipovich AH, Weisdorf D, Schubert MM, Shulman H, Schultz K, Mittelman B, Pavletic S, Vogelsang GB, Martin PJ, Lee SJ, Flowers ME. Ancillary therapy and supportive care of chronic graft-versus-host disease: national institutes of health consensus development project on criteria for clinical trials in chronic graft-versus-host disease: V. Ancillary Therapy and Supportive Care Working Group Report. *Biol Blood Marrow Transplant*. 2006; 12:375-96. PMID: 16545722
18. Ho VT, Kim HT, Liney D, Milford E, Gribben J, **Cutler C**, Lee SJ, Antin JH, Soiffer RJ, Alyea EP. HLA-C mismatch is associated with inferior survival after unrelated donor non-myeloablative hematopoietic stem cell transplantation. *Bone Marrow Transplant*. 2006;37(9):845-50. PMID: 16532020
19. Marty FM, Lowry CM, **Cutler CS**, Campbell BJ, Fiumara K, Baden LR, Antin JH. Voriconazole and sirolimus co-administration following allogeneic hematopoietic stem cell transplantation. *Biol Blood Marrow Transplant*. 2006; 12:552-9. PMID: 16635790
20. **Cutler C**, Miklos D, Kim HT, Treister N, Woo S-B, Bienfang D, Klickstein LB, Levin J, Miller K, Reynolds C, Macdonell R, Pasek M, Lee SJ, Ho V, Soiffer R, Antin JH, Ritz J, Alyea E. Rituximab for steroid-refractory chronic graft-vs.-host disease. *Blood*. 2006; 108:756-62. PMID: 16551963; PMCID: PMC1895490
21. Lee SJ, Kim HT, Ho VT, **Cutler C**, Alyea EP, Soiffer RJ, Antin JH. Quality of life associated with acute and chronic graft-versus-host disease. *Bone Marrow Transplant*. 2006; 38:305-10. PMID: 16819438
22. Alyea EP, Kim HT, Ho V, **Cutler C**, DeAngelo DJ, Stone R, Ritz J, Antin JH, Soiffer RJ. Impact of conditioning regimen intensity on outcome of allogeneic hematopoietic cell transplantation for advanced acute myelogenous leukemia and myelodysplastic syndrome. *Biol Blood Marrow Transplant*. 2006; 12:1047-55. PMID: 17067911
23. Brown JR, Kim HT, Li S, Stephans K, Fisher DC, **Cutler C**, Ho V, Lee SJ, Milford EL, Ritz J, Antin JH, Soiffer RJ, Gribben JG, Alyea EP. Predictors of improved progression-free survival after nonmyeloablative allogeneic stem cell transplantation for advanced chronic lymphocytic leukemia. *Biol Blood Marrow Transplant*. 2006; 12:1056-64. PMID: 17084369
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25. Koreth J, **Cutler CS**, Djulbegovic B, Behl R, Schlossman RL, Munshi NC, Richardson PG, Anderson KC, Soiffer RJ, Alyea EP 3rd. High-dose therapy with single autologous transplantation versus chemotherapy for newly diagnosed multiple myeloma: A systematic

- review and meta-analysis of randomized controlled trials. *Biol Blood Marrow Transplant*. 2007; 13:183-96. PMID: 17241924
26. **Cutler C**, Li S, Ho VT, Koreth J, Alyea E, Soiffer R, Antin JH. Extended follow-up of methotrexate-free immunosuppression using sirolimus and tacrolimus in related and unrelated donor peripheral blood stem cell transplantation. *Blood*. 2007;109: 3108-14. PMID: 17138818; PMCID: PMC1852220
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  28. Armand P, Kim HT, DeAngelo DJ, Ho VT, **Cutler CS**, Stone RM, Ritz J, Alyea EP, Antin JH, Soiffer RJ. Impact of cytogenetics on outcome of de novo and therapy-related AML and MDS after allogeneic transplantation. *Biol Blood Marrow Transplant*. 2007; 13(6):655-64. PMID: 17531775; PMCID: 2743535
  29. Marty FM, Bryar J, Browne SK, Schwarzberg T, Ho VT, Bassett IV, Koreth J, Alyea EP, Soiffer RJ, **Cutler CS**, Antin JH, Baden LR. Sirolimus-based graft-versus-host disease prophylaxis protects against cytomegalovirus reactivation after allogeneic hematopoietic stem cell transplantation: a cohort analysis. *Blood*. 2007; 110:490–500. PMID: 17392502; PMCID: PMC1924486
  30. Saito AM, Zahrieh D, **Cutler C**, Ho VT, Antin JH, Soiffer RJ, Alyea EP, Lee SJ. Lower costs associated with hematopoietic cell transplantation using reduced intensity vs. high-dose regimens for hematological malignancy. *Bone Marrow Transplant*. 2007; 40(3):209-17. PMID: 17563734
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  33. Schlenk RF, Pasquini MC, Pérez WS, Zhang MJ, Krauter J, Antin JH, Bashey A, Bolwell BJ, Büchner T, Cahn JY, Cairo MS, Copelan EA, **Cutler CS**, Döhner H, Gale RP, Ilhan O, Lazarus HM, Liesveld JL, Litzow MR, Marks DI, Maziarz RT, McCarthy PL, Nimer SD, Sierra J, Tallman MS, Weisdorf DJ, Horowitz MM, Ganser A on behalf of the CIBMTR Acute Leukemia Working Committee. HLA-identical sibling allogeneic transplants versus chemotherapy in acute myelogenous leukemia with t(8;21) in first complete remission: collaborative study between the German AML Intergroup and CIBMTR. *Biol Blood Marrow Transplant*. 2008;14(2):187-96. PMID: 18215779; PMCID: PMC2531160
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### **Narrative Report**

I am an Institute Physician in Medical Oncology at DFCI, an Associate Physician in Medical Oncology at BWH and an Associate Professor of Medicine at HMS. My Area of Excellence is Clinical Expertise and Innovation. I have Significant Supporting Activities of Investigation and Administration and Institutional Service.

Clinical Expertise and Innovation: I am a stem cell transplantation physician, devoting approximately half of my time to the care of patients with hematological malignancies undergoing allogeneic hematopoietic stem cell transplantation (HSCT). I attend on the inpatient stem cell transplantation service at BWH 6 weeks per year and in the ambulatory Stem Cell Transplantation clinic and the BMT Survivorship clinic at DFCI, 4 sessions per week, and 1 session per month, respectively. I also see patients in the Cutaneous Oncology clinic at DFCI one session per month.

My expertise in the prevention and treatment of acute and chronic graft-vs.-host-disease (GVHD) stems from years in clinical practice as well as the development of innovative drug-based approaches to the prevention and treatment of acute and chronic GVHD. Acute GVHD occurs in 35-55% of patients undergoing HSCT and is one of the most important causes of morbidity and mortality after HSCT. Over the past few years, I have developed a strategy to prevent acute GVHD using the novel immunosuppressant, sirolimus. This compound has now been tested in several clinical scenarios, including related and unrelated donor HSCT, and umbilical cord blood transplantation. As a result of these phase II investigations, sirolimus was tested in a randomized, phase III multicenter trial conducted by the Bone Marrow Transplant Clinical Trials Network where I served as the Principal Investigator. The results of this trial confirm that the combination of sirolimus and tacrolimus is an acceptable standard for GVHD prevention. This regimen has now become the standard of care at several centers both nationally and internationally. In addition to the prevention of acute GVHD, I am also developing novel therapeutics for the prevention and treatment of chronic GVHD. Chronic GVHD is the most important cause of late morbidity and mortality after allogeneic stem cell transplantation and occurs in up to 60% of HSCT survivors. I conducted the largest prospective trial of the monoclonal anti-B cell antibody, rituximab in chronic GVHD, and this compound is now considered standard-of-care therapy. Based on our work on B cells in chronic GVHD, we performed a trial of ibrutinib as therapy for chronic GVHD, leading to the FDA approval of this agent for this indication. Notably, this was the first drug approval for the therapy of GVHD granted by the FDA. Most recently, I have begun a clinical trial using a novel anti-B cell agent for prevention of chronic GVHD. This work is supported by a P01 award from the NIH, and I serve as the overall Principal Investigator. This grant incorporates elements of basic biology, murine modeling and clinical trials at several US centers. I am simultaneously testing several other interesting compounds for the treatment of established, steroid-resistant acute and chronic GVHD based on biological pathways and mechanisms discovered as part of our P01 grant.

Significant Supporting Activity: Investigation: I have spent 2 decades investigating the optimal role and timing of allogeneic stem cell transplantation for the Myelodysplastic syndromes. I have led a number of studies in this field, including a seminal decision analysis that was the first to demonstrate the utility of allogeneic transplantation for younger individuals. I currently am leading the national trial to demonstrate superiority of allogeneic stem cell transplantation in comparison to non-transplant therapies. This trial will include outcome measures such as cost-effectiveness and quality of life. Additionally, I have been involved in several national efforts to address the Centers for Medicare Services Coverage with Evidence Determination program. In addition to work in MDS, I perform studies in umbilical cord blood transplantation and lead the DF/HCC cord blood program.

Significant Supporting Activity: Administration and Institutional Service: My administrative responsibilities now include the overall supervision of the Stem Cell Transplantation Program as Medical Director. I have managed our Division's Research portfolio, established a successful Advanced Transplantation Fellowship Program and am responsible for starting our successful Survivorship Program as well. I have served as the Treasurer of the American Society for Blood and Marrow Transplantation for the past 6 years and serve on a number of committees for the Center for International Blood and Marrow Transplantation Research.

Teaching: I have several teaching responsibilities in addition to teaching and supervising fellows in hematology/oncology at the DFCI. I teach clinical trial design and methodology at an annual research training course for fellows and junior faculty in transplantation, sponsored by the American Society for Transplantation and Cellular Therapy. I established an advanced Fellowship Program in Stem Cell Transplantation which has been accredited by Partners, and we currently have accepted our 5th fellow into this program.