

BIOGRAPHICAL SKETCH

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NAME: Patrick J Stiff MD

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

POSITION TITLE: Senior Professor of Medicine

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 Toledo; Toledo OH	BS (ACS)	03/7192	Chemistry
Loyola University, Stritch School of Medicine; Maywood, IL	MD	09/1975	Medicine
Cleveland Clinic; Cleveland OH	Postdoctoral	06/1978	Internal Medicine, Residency
Memorial Sloan-Kettering Cancer Center, NY,NY	Postdoctoral	06/1981	Hematology-Oncology, Fellowship

A. Personal Statement

I am currently Senior Professor of Medicine in the Department of Medicine at Loyola University Stritch School of Medicine. I have a long history of significant research in Bone Marrow Transplantation starting during my Fellowship when I developed a novel 2-agent cryoprotectant for hematopoietic stem cells using hydroxyethyl starch and dimethylsulfoxide that is used worldwide and was shown in a Phase III trial to provide superior neutrophil engraftment after autologous transplantation. I performed some of the first peripheral blood stem cell transplants collecting stem cells during the rebound after aggressive chemotherapy and later did significant work defining the use of cytokines both in collecting stem cells and in their use in the recovery period after transplantation. Subsequently, I performed the first autotransplants using stem cells collected from small aliquots of bone marrow harvested in the clinic and grown in bioreactors. This led to significant work in the ex vivo expansion of umbilical cord blood stem cells, that has ultimately led to licensing of the Gamida cell Nicord product in April 2023 by the US FDA. Currently as the Chair of the Blood and Marrow Stem Cell Committee for SWOG, I mentor currently junior faculty in their transplant and CAR-T research projects in Non-Hodgkin's Lymphoma, multiple myeloma, and amyloidosis. I also currently serve as Co-Chair of the NIH Myelo-MATCH Transplant Committee, developing novel transplant therapies in Acute Myeloid Leukemia and Myelodysplasia nationally for the NCTN network. My personal work is in co-developing a novel system using exosomes to produce CD4 and CD8 cells from cord blood stem cells to have these available for patients as a form of donor lymphocyte infusions post allograft and to boost anti-infection immunity. A new project with Katherine Knight PhD capitalizes on a long career of managing patients undergoing allogeneic bone marrow transplantation, and in working with industry and the national BMT-CTN network that is focused on developing novel ways to both prevent and treat acute and chronic graft vs host disease. I assisted her in focusing the strategy of her ongoing EPS work to prevent/treat acute GVHD and helped to design her next series of experiments. Based

on the successful completion of these experiments, I will design and implement the first in man Phase I trial that we hope will lead to a new prophylaxis regimen for all allogeneic stem cell transplants.

B. Positions, Scientific Appointments, and Honors

1975 – 1978:	Resident in Internal Medicine and Senior Resident in Internal Medicine; Cleveland Clinic; Cleveland, OH
1978 – 1981	Research Fellow in Medical Oncology; Memorial Sloan-Kettering Cancer Center; New York
1979 – 1981	Assistant Clinical Instructor in Medicine; Cornell University Medical College; New York, NY
1981 – 1986	Assistant Professor of Medicine; Director, Bone Marrow Transplantation Service; Division of Hematology/Oncology; Southern Illinois Univ. School of Medicine; Springfield, IL
1986 – 1991	Assistant Professor of Medicine; Director, Bone Marrow Transplantation Program Division of Hematology/Oncology; Loyola Stritch School of Medicine; Maywood, IL
1991 - 1998	Associate Professor of Medicine; Director, Bone Marrow Transplantation Program Division of Hematology/Oncology; Loyola Stritch School of Medicine; Maywood, IL
1998 – 2020	Coleman Professor of Medicine and Pathology; Director, Bone Marrow Transplantation Program; Division of Hematology/Oncology; Loyola Stritch School of Medicine; Maywood, IL
2003 – 2020	Director, Division of Hematology/Oncology; Loyola Stritch School of Medicine; Maywood, IL
2003 – 2018	Director, Cardinal Bernardin Cancer Center; Loyola University Stritch School of Medicine
2017---present	Core Group Consortium Member Institution PI, BMT-CTN (NHLBI-NCI funded)
2022—present	Senior Professor of Medicine, Loyola University Stritch School of Medicine

Awards:

1975	Alpha Omega Alpha (3 rd year student inductee)
2012	Arnold Damen, S.J. Award; Stritch School of Medicine, Loyola University, Chicago
2012	Selected to “The One Hundred”: Mass General Hospital
2012- 2022	Chair, Medical Advisory Committee, Leukemia Research Foundation
2013- present	Chair, SWOG Bone Marrow & Stem Cell Transplantation Committee
2016	Recipient Stritch Medal, Loyola University-Chicago
2022-present	Co-chair MyeloMATCH Transplantation Tier

C. Contributions to Science

I have long initiated translational research programs throughout my career, starting with my fellowship:

- Using *ex vivo* HSC expansion in stromal-based perfusion bioreactors, I first reported the successful autologous stem cell transplantation grown from a small aliquot of bone marrow. Such techniques were utilized in cord blood transplantation and in collaboration with basic researchers and other clinicians, we developed several *ex vivo* expansion systems for cord blood HSCs. We are currently researching techniques to solve the key problems of cord blood stem cell transplantation, most recently the immune system, and are involved in DC vaccine work for ovarian cancer.
- Horwitz ME, **Stiff PJ**, Cutler C, Brunstein C, Hanna R, Maziarz RT, Rezvani AR, Karris NA, McGuirk J, Valcarcel D, Schiller GJ, Lindemans CA, Hwang WYK, Koh LP, Keating A, Khaled Y, Hamerschlak N, Frankfurt O, Peled T, Segalovich I, Blackwell B, Wease S, Freedman LS, Galamidi-Cohen E, Sanz G. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. *Blood*. 2021 Oct 21;138(16):1429-1440. doi: 10.1182/blood.2021011719.
- de Koning C, Tao W, Lacna A, van Veghel K, Horwitz ME, Sanz G, Jagasia MH, Wagner JE, **Stiff PJ**, Hanna R, Cilloni D, Valcárcel D, Peled T, Galamidi Cohen E, Goshen U, Pandit A, Lindemans CA, Jan Boelens J, Nierkens S. Lymphoid and myeloid immune cell reconstitution after nicotinamide-expanded cord blood transplantation. *Bone Marrow Transplant*. 2021 Nov;56(11):2826-2833. doi: 10.1038/s41409-021-01417-4. Epub 2021 Jul 26.
- **PJ Stiff**, P Montesinos, T Peled, E Landau, NR Goudsmid, J Mandel, N Hasson, E Olesinski, E Glukhman, DA Snyder, EG Cohen, OS Kidron, D Bracha, D Harati, K Ben-Abu, E Freind, LS Freedman, YC Cohen, L Olmer, R Barishev, V Rocha, E Gluckman, MM Horowitz, M Eapen, A Nagler, and G Sanz. Cohort-controlled comparison of umbilical cord blood transplantation using carlecortemcel-L, a single progenitor-enriched cord blood, to double cord blood unit transplantation. *Biol Blood Marrow Transplant*. 2018

Jul;24(7):1463-1470. doi: 10.1016

- Sobol U, Go A, Kliethermes S, Bufalino S, Rodriguez T, Smith S, Parthasarathy M, **Stiff P**. A prospective investigation of cell dose in single-unit umbilical cord blood transplantation for adults with high-risk hematologic malignancies. *Bone Marrow Transplant*. 2015 Dec;50(12):1519-25
- Horwitz ME, Chao NJ, Rizzieri DA, Long GD, Sullivan KM, Gasparetto C, Chute JP, Morris A, McDonald C, Waters-Pick B, **Stiff P**, Wease S, Peled A, Snyder D, Cohen EG, Shoham H, Landau E, Friend E, Peleg I, Aschengrau D, Yackoubov D, Kurtzberg J, Peled T. Umbilical cord blood expansion with nicotinamide provides long-term multilineage engraftment. *J Clin Invest*. 2014 Jul 1;124 (7):3121-8
- Beaudette-Zlatanova B, Le P, Knight K, Zhong S, Zakrzewski S, Parthasarathy M, **Stiff PJ**. A potential role for B-cells immunosuppressed immune responses in cord blood transplant recipients. *Bone Marrow Transplant* 2012 June 25,

- I have developed novel immunotherapy approaches for human malignancies in addition to working with CAR-T cells This includes the development of IND supported immunotherapy for *ex vivo* expansion of functional dendritic cells for clinical immunotherapy of ovarian cancer currently (BB IND 13717), but my work also has included acute leukemia.
- Neelapu SS, Jacobson CA, Ghobadi A, Miklos DB, Lekakis LJ, Oluwole OO, Lin Y, Braunschweig I, Hill BT, Timmerman JM, Deol A, Reagan PM, **Stiff P**, Flinn IW, Farooq U, Goy AH, McSweeney PA, Munoz J, Siddiqi T, Chavez JC, Herrera AF, Bartlett NL, Bot AA, Shen RR, Dong J, Singh K, Miao H, Kim JJ, Zheng Y, Locke FL. Five-year follow-up of ZUMA-1 supports the curative potential of axicabtagene ciloleucel in refractory large B-cell lymphoma. *Blood*. 2023 May 11;141(19):2307-2315. doi: 10.1182/blood.2022018893.
- Shah BD, Ghobadi A, Oluwole OO, Logan AC, Boissel N, Cassaday RD, Leguay T, Bishop MR, Topp MS, Tzachanis D, O'Dwyer KM, Arellano ML, Lin Y, Baer MR, Schiller GJ, Park JH, Subklewe M, Abedi M, Minnema MC, Wierda WG, DeAngelo DJ, **Stiff P**, Jeyakumar D, Dong J, Adhikary S, Zhou L, Schuberth PC, Faghmous I, Masouleh BK, Houot R.J Two-year follow-up of KTE-X19 in patients with relapsed or refractory adult B-cell acute lymphoblastic leukemia in ZUMA-3 and its contextualization with SCHOLAR-3, an external historical control study. *Hematol Oncol*. 2022 Dec 10;15(1):170. doi: 10.1186/s13045-022-01379-0.
- Hossain NM, **Stiff PJ** Expanding the Toolbox of Adoptive Cell Immunotherapy. *J Clin Oncol*. 2021 May 1;39(13):1479-1482. doi: 10.1200/JCO.21.00295. Epub 2021 Mar 25.PMID: 33764792
- Locke FL, Ghobadi A, Jacobson CA, Miklos DB, Lekakis LJ, Oluwole OO, Lin Y, Braunschweig I, Hill BT, Timmerman JM, Deol A, Reagan PM, Stiff P, Flinn IW, Farooq U, Goy A, McSweeney PA, Munoz J, Siddiqi T, Chavez JC, Herrera AF, Bartlett NL, Wiezorek JS, Navale L, Xue A, Jiang Y, Bot A, Rossi JM, Kim JJ, Go WY, Neelapu SS. Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1-2 trial. *Lancet Oncol*. 2019 Jan;20(1):31-42. doi: 10.1016/S1470-2045(18)30864-7. Epub 2018 Dec 2.
- Drakes ML, **Stiff PJ**. Regulation of Ovarian cancer Prognosis by Immune Cells in the Tumor Microenvironment. *Cancers*, 2018, 10, 302; doi:10.3390/cancers 10090302
- Neelapu SS, Locke FL, Bartlett NL, Lekakis LJ, Miklos DB, Jacobson CA, Braunschweig I, Oluwole OO, Siddiqi T, Lin Y, Timmerman JM, **Stiff PJ**, Friedberg JW, Flinn IW, Goy A, Hill BT, Smith MR, Deol A, Farooq U, McSweeney P, Munoz J, Avivi I, Castro JE, Westin JR, Chavez JC, Ghobadi A, Komanduri KV, Levy R, Jacobsen ED, Witzig TE, Reagan P, Bot A, Rossi J, Navale L, Jiang Y, Aycock J, Elias M, Chang D, Wiezorek J, Go WY. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. *N Engl J Med*. 2017 Dec 28;377(26):2531-2544. doi: 10.1056/NEJMoa1707447
- Khoury HJ, Collins RH Jr, Blum W, **Stiff PS**, Elias L, Lebkowski JS, Reddy A, Nishimoto KP, Sen D, Wirth ED 3rd, Case CC, DiPersio JF. Immune responses and long-term disease recurrence status after telomerase-based dendritic cell immunotherapy in patients with acute myeloid leukemia. *Cancer*. 2017 Apr 14. doi: 10.1002/cncr.30696. [Epub ahead of print]

- Transplantation of Malignant lymphomas. I led 4 SWOG national trials in BMT. Most recently, I led the international team that reported on the efficacy of autologous stem cell transplantation for diffuse aggressive NHLs in first remission. I wrote the protocol, analyzed each chart, wrote the manuscript which got published at the New England Journal of Medicine. There have been 2 subgroup analyses performed

on this data set; 2 are published, the third (T-cell subset) has been published. This work continues in my role as Chair of the Blood and Marrow Transplant Committee for SWOG. I wrote the protocol and mentored the revisions the combined SWOG-BMT-CTN tandem autograft trial manuscript for Hodgkin's Lymphoma, published.

- Nademanee A, Sureda A, **Stiff P**, Holowiecki J, Abidi M, Hunder N, Pecsok M, Uttarwar M, Purevjal I, Sweetenham J. Safety Analysis of Brentuximab Vedotin from the Phase III AETHERA Trial in Hodgkin Lymphoma in the Post-Transplant Consolidation Setting. *Biol Blood Marrow Transplant*. 2018 May 30. pii: S1083-8791(18)30298-2
 - Smith EP, Li H, Friedberg JW, Constine LS, Rimsza LM, Cook JR, Laport GG, Popplewell LL, Holmberg LA, Smith SM, LeBlanc M, Forman SJ, Fisher RI, **Stiff PJ**. Tandem Autologous Hematopoietic Cell Transplantation for Patients with Primary Progressive or Recurrent Hodgkin Lymphoma: a SWOG and Blood & Marrow Transplant Clinical Trials Network Phase II Trial (SWOG S0410/BMT CTN 0703).

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Biol Blood Marrow Transplant. 2017 Dec 28. pii: S1083-8791(17)31830-X. doi: 10.1016
 - Puvvada SD, **Stiff PJ**, Leblanc M, Cook JR, Couban S, Leonard JP, Kahl B, Marcellus D, Shea TC, Winter JN, Li H, Rimsza LM, Friedberg JW, Smith SM. Outcomes of MYC-associated lymphomas after R-CHOP with and without consolidative autologous stem cell transplant: subset analysis of randomized trial intergroup SWOG S9704 *Br J Haematol*. 2016 Sep;174(5):686-91. doi: 10.1111/bjh.14100
 - Moskowitz CH, Nademanee A, Masszi T, Agura E, Holowiecki J, Abidi MH, Chen AI, **Stiff P**, Gianni AM, Carella A, Osmanov D, Bachanova V, Sweetenham J, Sureda A, Huebner D, Sievers EL, Chi A, Larsen EK, Hunder NN, Walewski J; AETHERA Study Group. Brentuximab vedotin as consolidation therapy after autologous stem-cell transplantation in patients with Hodgkin's lymphoma at risk of relapse or progression (AETHERA): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2015 May 9;385(9980):1853-62
 - I am the first of several physicians to initiate mobilized peripheral blood stem cell transplantation therapy for leukemia and solid tumors. I developed and evaluated several HSC mobilization protocols to optimize HSC mobilization efficiency, particularly for these hard-to-mobilize patients.
 - Micallef IN, **Stiff PJ**, Nademanee AP, Maziarz RT, Horwitz ME, Stadtmauer EA, Kaufman JL, McCarty JM, Vargo R, Cheverton PD, Struijs M, Bolwell B, DiPersio JF. Plerixafor Plus Granulocyte Colony-Stimulating Factor for Patients with Non-Hodgkin Lymphoma and Multiple Myeloma: Long-Term Follow-Up Report. *Biol Blood Marrow Transplant*. 2018 Jun;24(6):1187-1195. doi: 10.1016/j
 - Micallef IN, **Stiff PJ**, Stadtmauer EA, Bolwell BJ, Nademanee AP, Maziarz RT, Partisano AM, Marulkar S, DiPersio JF. Safety and efficacy of upfront plerixafor + G-CSF vs placebo + G-CSF for mobilization of CD34(+) hematopoietic progenitor cells in patients >60 and <60 years of age with non-Hodgkin's lymphoma or multiple myeloma. *Am J Hematol*. 2014 Dec: 88(12): 1017-23.
 - **Stiff P**, Micallef I, McCarthy P, Magalhaes-Silverman M, Weisdorf D, Territo M, Badel, K, Calandra G. Treatment with Plerixafor in non-Hodgkin's lymphoma and multiple myeloma patients to increase the number of peripheral blood stem cells when given a mobilizing regimen of G-CSF: implications for the heavily pre-treated patients. *Biol Blood Marrow Transplantation*. 2009 Feb;15(2):249-56.
 - Maziarz RT, Nademanee AP, Micallef IN, **Stiff PJ**, Calandra G, Angell J, Dipersio JF, Bolwell BJ. Plerixafor Plus Granulocyte Colony-Stimulating Factor Improves the Mobilization of Hematopoietic Stem Cells in Patients with Non-Hodgkin Lymphoma and Low Circulating Peripheral Blood CD34(+) Cells. *Biol Blood Marrow Transplant*. 2013 Apr;19(4):670-5
5. I have participated in graft vs host disease and associated immune reconstitution studies and assessments over the years and continue to be involved in research efforts to mitigate against this allogeneic transplantation complication
- Zeiser R, Polverelli N, Ram R, Hashmi SK, Chakraverty R, Middeke JM, Musso M, Giebel S, Uzay A, Langmuir P, Hollaender N, Gowda M, Stefanelli T, Lee SJ, Teshima T, Locatelli F; REACH3 Investigators. Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease. *N Engl J Med*. 2021 Jul 15;385(3):228-238. doi: 10.1056/NEJMoa2033122.

- Hagen PA, Adams W, Smith S, Tsai S, **Stiff P** Low mean post-transplantation tacrolimus levels in weeks 2-3 correlate with acute graft-versus-host disease in allogeneic hematopoietic stem cell transplantation from related and unrelated donors. **P**. Bone Marrow Transplant. 2019 Jan;54(1):155-158. doi: 10.1038/s41409-018-0267-5. Epub 2018 Jul 23.
- Szabolcs P, Mazor RD, Yackoubov D, Levy S, **Stiff P**, Rezvani A, Hanna R, Wagner J, Keating A, Lindemans CA, Karras N, McGuirk J, Hamerschlak N, López-Torija I, Sanz G, Valcarcel D, Horwitz ME. Immune Reconstitution Profiling Suggests Antiviral Protection after Transplantation with Omidubicel: A Phase 3 Substudy. Transplant Cell Ther. 2023 Apr 28:S2666-6367(23)01256-3. doi: 10.1016/j.jtct.2023.04.018.