BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Spears, Patricia A.

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

POSITION TITLE: Scientific Research Manager, Patient Advocacy Specialist

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
North Carolina State University, Raleigh, NC	B.S.	05/1984	Biology/Microbiology

A. Personal Statement

I am currently an active advocate for cancer research and clinical trials. I am devoted to science and have a Bachelor of Science degree in biology/microbiology and extensive laboratory experience in molecular biology. I am also an over 20-year survivor of breast cancer and survivor of liver cancer. The inquisitive nature of being a scientist and having an understanding of scientific concepts along with my personal experience through cancer treatment (including 2 clinical trials) fits well with being a cancer research advocate. As an advocate on research projects, I can bring an outside perspective and add urgency to the translational potential of the project. Scientific endeavors are exciting, but they have to be done with an outcome that benefits patients. My goal through research advocacy is to further my contribution in the conduct of research as well as the design and implementation of clinical trials that brings the best research to the clinic to benefit patients. In my current position in research management and patient advocacy at UNC Lineberger Comprehensive Cancer Center, I can further impact clinical and translational research on both the local and national levels.

1. **Spears, PA**, Patient engagement in cancer research from the patient's perspective, Future Oncology, Published Online:2 Jul 2021 PubMed PMID: 34213358
2. Kim ES, Uldrick TS, Schenkel C, Bruinooge SS, Harvey RD, Magnuson A, Spira A, Wade JL, Stewart MD, Vega DM, Beaver JA, Denicoff AM, Ison G, Ivy SP, George S, Perez RP, **Spears PA**, Tap WD, Schilsky RL. Continuing to Broaden Eligibility Criteria to Make Clinical Trials More Representative and Inclusive: ASCO-Friends of Cancer Research Joint Research Statement. Clin Cancer Res. 2021 Feb 9. doi: 10.1158/1078-0432.CCR-20-3852. Epub ahead of print. PMID: 33563632.
3. Basch E, Schrag D, Henson S, Jansen J, Ginos B, Stover AM, Carr P, **Spears PA**, Jonsson M, Deal AM, Bennett AV, Thanarajasingam G, Rogak LJ, Reeve BB, Snyder C, Bruner D, Cella D, Kottschade LA, Perlmutter J, Geoghegan C, Samuel-Ryals CA, Given B, Mazza GL, Miller R, Strasser JF, Zylla DM, Weiss A, Blinder VS, Dueck AC. Effect of Electronic Symptom Monitoring on Patient-Reported Outcomes Among Patients With Metastatic Cancer: A Randomized Clinical Trial. JAMA. 2022 Jun 5. doi: 10.1001/jama.2022.9265. Epub ahead of print. PMID: 35661856.
4. Wolff AC, Hammond MEH, Allison KH, Harvey BE, Mangu PB, Bartlett JMS, Bilous M, Ellis IO, Fitzgibbons P, Hanna W, Jenkins RB, Press MF, **Spears PA**, Vance GH, Viale G, McShane LM, Dowsett M. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. J Clin Oncol. 2018 May 30:JCO2018778738. doi: 10.1200/JCO.2018.77.8738. [Epub ahead of print] PMID: 29846122

B. Positions, Scientific Appointments and Honors

Positions and Employment

2018-present	Associate Group Chair for Advocacy, Alliance for Clinical Trials in Oncology
2017-present	Scientific Research Manager and Patient Advocacy, UNC Lineberger Comp. Cancer Cent.
2007-2017	Research Specialist, Advanced, North Carolina State University, Coll. of Vet. Med.
2001-2007	Research Technician III, North Carolina State University, Coll. of Vet. Med
1997-2001	Research Scientist, North Carolina State University, Coll. of Vet. Med.
1994-1997	Scientist, Becton Dickinson Research Center
1992-1994	Research Associate II, Becton Dickinson Research Center
1991-1992	Research Associate I, Becton Dickinson Research Center
1987-1990	Research Assistant, Brown University
1986-1987	Research Assistant II, Harvard Medical School
1984-1986	Research Technician III, North Carolina State University, Coll. of Vet. Med

Other Professional Affiliations, Teaching, Honors and Trainings

Professional Affiliations

2020 – present	Society for Immunotherapy of Cancer (SITC)
2016 - present	American Society of Clinical Oncology (ASCO)
2016 - present	American Association for Cancer Research (AACR)
1992-2016	American Society for Microbiology (ASM)

Teaching

2020-present	University of North Carolina, Patients and Community Engagement to Educate Researchers (PEER), Trainee lectures on patient engagement and communicating science to the public.
2019	University of North Carolina Gillings School of Global Public Health, Patient-Reported Outcomes Measurement and Application in Healthcare Research and Practice, HPM 794, Lecture
2017-present	University of North Carolina Gillings School of Global Public Health, Cancer Epidemiology: Survivorship and Outcomes, EPID 771, Lecture
2013-present	Duke Cancer Institute, Translational Aspects of Pathobiology, PATH 786, Lecture
2013-2015	Laboratory Teaching Assistant, Problem Solving Cases Infectious Disease & Immunity 2, VMP934
2008-2012	Guest Laboratory Lecture, Pathogenic Bacteriology and Mycology VMP914, Molecular Diagnostic Microbiology
2008-2010	Lecturer, Senior Rotation in Microbiology VMP977
2006-2015	Laboratory Teaching Assistant, Pathogenic Bacteriology and Mycology, VMP914/910

Honors

2023	ASCO 2023 class of Fellows of the American Society of Clinical Oncology (FASCO)
2022	ASCO 2022 Patient Advocate Award
2020	AACR 2020 Distinguished Public Service Award
2018	Susan G. Komen Triangle to the Coast Affiliate, Spirit to Inspire Award
2015	Susan G. Komen Triangle Race for the Cure Jeanne Peck Award
2010-2019	Susan G. Komen for the Cure, Komen Scholar, Advocate Member
2007	National Cancer Institute, caBIG™ Patient Advocate Award
2003	Susan G. Komen NC Triangle Affiliate, Maureen Jordan-Thomas Spirit of Survivorship Award
2002	Susan G. Komen, New Volunteer of the Year Award

Cancer Advocacy Trainings

2022	Research Advocacy Network/ASCO, Critical Thinking for Grant Reviewers
2021	Research Advocacy Network, Advancing Health Equity: Empowering Advocates Course
2021	Research Advocacy Network, Precision Medicine in Oncology Series 2021
2019	Susan G. Komen Advocates in Science, Big Data for Patients Training, Participant
2018	American Association for Cancer Research (AACR), Scientist<->Survivor Program, Mentor
2016-18	Accelerating Anticancer Agent Development and Validation Advocate Fundamentals and Workshop, Participant
2016	American Association for Cancer Research, Scientist<->Survivor Program participant

2007 American Association for Cancer Research, Scientist<->Survivor Program participant
2003 National Breast Cancer Coalition, Project LEAD® Graduate

C. Contributions to Science

1. I have contributed to the conduct of clinical trials from the local level at UNC Lineberger and Duke Cancer Institute to the National level as an Alliance for Clinical Trials in Oncology advocate. I served as the inaugural patient advocate member of the National Cancer Institute's Breast Cancer Steering Committee (BCSC) from 2009-13 and again from 2019-2021. I am now on the Investigational Drug Steering Committee (IDSC) and am co-Chair of the Patient Advocate Steering Committee (PASC). I also serve on the Clinical Trials and Translational Research Advisory Committee (CTAC) of the NCI. The significance of my contributions is to bring the patient voice to the development of National Clinical Trials Network (NCTN) and all clinical trials. It is important to maintain an understanding of the conduct of clinical trials and be able to speak on behalf of all patients. I have been involved with CALGB since 2008 and am now Chair of the Patient Advocate Committee and am currently the Associate Group Chair for Advocacy of the Alliance for Clinical Trials in Oncology. At the University of North Carolina, I review consent forms and patient materials for content and readability. I also have the opportunity to train other advocates to be partners in the conduct of clinical trials. I am currently serving as the UNC representative to the TBCRC. In my role as advocate I interacted with researchers from all member institutions.

    a. **Spears, P.,** Words Matter, Oncobites blog, February 2020.
    b. **Spears, P.,** Getting Cancer Treatment Right: when more is not always better, November 2019
    c. **Spears, P.,** Listen to Me, OncoBites blog, July 2019
    d. **Spears, PA.** Patient barriers to participation in breast cancer clinical trials, 2020 Breast Cancer Management. 9:1 Editorial. Published Online:3 Mar 2020

2. I have participated in multiple panels and review committees sponsored by various organizations including the U. S. Food and Drug Administration (FDA), American Society of Clinical Oncology (ASCO), College of American Pathologists (CAP), American Association for Cancer Research (AACR), Breast Cancer Research Foundation (BCRF), Accelerating Anticancer Agent Development and Validation (AAADV) and Friends of Cancer Research (FOCR). Being able to participate on panels and committees where key determinations are made that have an impact on patient care is important. I have had the opportunity to participate on two pivotal panels in breast cancer. I continue to be a member of the ASCO-CAP HER-2 Testing in Breast Cancer Guideline, which resulted in writing the patient and clinician communication section of a publication as well as web site, which I contributed to the final design. I have participated in several guideline panels and wrote a blog for ASCO Cancer.net about participating in guideline panels. I have had the opportunity to participate in several FDA breast cancer panels of significance and have been on 2 FDA Oncologic Drugs Advisory Committees in 2016 and 2017. My focus on patient reported outcomes have led to presenting at an NCI workshop on the incorporation of PROs into precision medicine trials and several FDA panels about Clinical Outcomes Assessments (COAs). It is important to assess the use of PROs in all NCI trials by engaging all stakeholders including patients. I have spoken several times on PROs in multiple venues including DIA, FOCR, FDA cPATH, and pharmaceutical companies.

    a. HER2 Testing for Breast Cancer, October 7, 2013, Website content and infographic development for general public on ASCO Cancer.net website
    b. **Spears, P.,** 2017, How Advocates Help Create Guidelines, March 24, ASCO Cancer.net,
    c. Schilsky, RL., M Mooney, A. Murgo, T. Saks, **P. Spears**. PANEL 2 Evidence for Use of Maintenance Therapy. Friends of Cancer Research Issue Brief, Conference on Clinical Cancer Research, November 2011.
    d. Basch, E., A. Campbell, D. Globe, P. Kluetz, M. Kozak, L. Minasian, S. Mitchell, E. Richardson, **P. Spears**. Panel Two – Capturing Symptomatic Adverse Events From the Patients' Perspective: The Potential Role of the National Cancer Institute's PRO-CTCAE Measurement System. Friends of Cancer Research Issue Brief, Conference on Clinical Cancer Research, November, 2015.

3. I have had the opportunity to work on key research projects. Being involved with research at University of North Carolina at Chapel Hill and Duke Cancer Institute has given me exposure into basic research, translational research and the conduct of early first-in-human clinical trials. Getting to know the laboratory members conducting the research ensures they know a patient and instills a sense of urgency to their work. Since 2012 I have been involved in two Department of Defense funded projects at Duke, a Transformative Vision Award and a Clinical Translational Research Award. I am currently an advocate on a 2021 Transformative Breast Cancer Consortium Award. The PI of all three is Dr. H. Kim Lyerly. I am a member of the UNC Breast Cancer SPORE, where I organize the Advocacy Core. The Core has 8 advocates dedicated to work with each SPORE research project. I have been involved as a patient partner/investigator on several PCORI projects, PIs C. Greenberg (Alliance), E. Basch (PRO-PM, UNC), E. Basch (PRO-TECT, Alliance). I work closely with Dr. Ethan Basch and Dr. Angela Stover, on the PCORI projects are at UNC and a more recently funded Moonshot project. I am also a patient partner on 2 additional studies, PCORI project, Patient Centered Research for Standards of Outcomes in Diagnostic Tests: The PROD Study, University of Washington in Seattle, M. Thompson PI and NIH, Addressing Ethical Issues in Unregulated Health Research Using Mobile Devices, Mark Rothstein, PI. I am also involved in the Perou laboratory at UNC, where I am a patient advocate on several funded projects and participate in their weekly lab meeting. I have recently joined the Stand Up 2 Meg Vosberg T-Cell Lymphoma Dream Team and will be presenting a poster at the 2020 SU2C Annual Summit.

    a. Basch E, Stover AM, Schrag D, Chung A, Jansen J, Henson S, Carr P, Ginos B, Deal A, **Spears PA**, Jonsson M, Bennett AV, Mody G, Thanarajasingam G, Rogak LJ, Reeve BB, Snyder C, Kottschade LA, Charlot M, Weiss A, Bruner D, Dueck AC. Clinical Utility and User Perceptions of a Digital System for Electronic Patient-Reported Symptom Monitoring During Routine Cancer Care: Findings From the PRO-TECT Trial. JCO Clin Cancer Inform. 2020 Oct;4:947-957. doi: 10.1200/CCI.20.00081. PMID: 33112661. PMCID: PMC7768331
    b. Shepherd JH, Ballman K, Polley MC, Campbell JD, Fan C, Selitsky S, Fernandez-Martinez A, Parker JS, Hoadley KA, Hu Z, Li Y, Soloway MG, Spears PA, Singh B, Tolaney SM, Somlo G, Port ER, Ma C, Kuzma C, Mamounas E, Golshan M, Bellon JR, Collyar D, Hahn OM, Hudis CA, Winer EP, Partridge A, Hyslop T, Carey LA, Perou CM, Sikov WM. CALGB 40603 (Alliance): Long-Term Outcomes and Genomic Correlates of Response and Survival After Neoadjuvant Chemotherapy With or Without Carboplatin and Bevacizumab in Triple-Negative Breast Cancer. J Clin Oncol. 2022 Jan 19:JCO2101506. doi: 10.1200/JCO.21.01506. Epub ahead of print. PMID: 35044810.
    c. Schumacher JR, Neuman HB, Yu M, Vanness DJ, Si Y, Burnside ES, Ruddy KJ, Partridge AH, Schrag D, Edge SB, Zhang Y, Jacobs EA, Havlena J, Francescatti AB, Winchester DP, McKellar DP, **Spears PA**, Kozower BD, Chang GJ, Greenberg CC; Alliance ACS-CRP CCDR Breast Cancer Surveillance Working Group. Surveillance imaging vs symptomatic recurrence detection and survival in stage II-III breast cancer (AFT-01). J Natl Cancer Inst. 2022 Aug 1:djac131. doi: 10.1093/jnci/djac131. Epub ahead of print. PMID: 35913454.
    d. Ligibel JA, Barry WT, Alfano C, Hershman DL, Irwin M, Neuhouser M, Thomson CA, Delahanty L, Frank E, **Spears P**, Paskett ED, Hopkins J, Bernstein V, Stearns V, White J, Hahn O, Hudis C, Winer EP, Wadden TA, Goodwin PJ. Randomized phase III trial evaluating the role of weight loss in adjuvant treatment of overweight and obese women with early breast cancer (Alliance A011401): study design. NPJ Breast Cancer. 2017 Sep 21;3:37. doi: 10.1038/s41523-017-0040-8. eCollection 2017. Review

4. I have been involved in many educational activities providing the development or delivery of trainings and scientific information to the public and advocates. In 2014 I was asked to give a presentation on How to Approach the Patient to Enroll in Clinical Trials in the Enrolling Patients on Clinical Trials: The Nuts and Bolts session at the *American College of Surgeons Clinical Congress.* In 2015 I participated in a panel on Integrating Patient Reported Outcomes (PROs) into Regulatory Evaluation at the *AACR Annual Meeting*, where I provided the patient perspective. Prior to the conference I conducted a survey of advocates on their thoughts about PROs in clinical trials and presented those results. I also presented this data as a poster at the 2016 SABCS. Since 2015 I have participated as a planning committee member, speaker and participant in the Accelerating Anticancer Agent Development and Validation Workshop and the advocate Fundamentals Workshop. I have participated as a panel member at the 2017 San Antonio Breast Cancer Symposium session called “View from the Trenches” and in 2019 presented a talk about “How to talk to

patients about clinical trials". In 2022 I participated in several SABCS sessions including a presentation on PROs in an Education Session. I have also served on the planning committees for the 2019 AACR Annual Meeting and for the 2021 and 2022 AACR SABCS meetings. This allows me the opportunity of ensuring the voice of the patient is present throughout. I also recorded a talk on engaging advocates in your research for ASCO Young Investigator Awards applicants. I currently lead the UNC Patient Advocates for Research Council and have given several advocate trainings on grant review and how to write a biosketch and letters of support.

a. Your Immune System and Cancer Treatment, Cancer Support Community, Frankly Speaking about Cancer, August 2015. On Cancer Support Community website
b. **Spears, P**. Integrating Patient Reported Outcomes (PROs) into Regulatory Evaluation, Patient Perspective, 2015 AACR Annual Meeting &.
c. Research Advocacy Website. Cancer Information and Support Network, content development. 2014. On cisncancer website
d. **Spears, P.** and D. Collyar. Beyond Patient Engagement: How Research Patient Advocates (RPAs) Contribute to Product Development. DIA Global Forum, September 2017, 9(6) pgs 14-15.

5. I have been an advocate reviewer of research grants since 2003. I have reviewed grants for several organizations including Susan G. Komen (SGK), Patient Centered Outcomes Research Institute (PCORI), ASCO Young Investigator Awards and Department of Defense (CDMRP). This is an area that I think I am uniquely qualified, since I understand the science of the proposals, but I also understand the mindset of patients, since I am a breast cancer survivor. I have been involved in many aspects including mentoring, training and assessment of advocate reviewers in peer review. In my role at UNC I manage the incorporation of the patient and community voice in the LCCC Developmental Funding Program each Spring and Fall. I recruit and train advocate reviewers and mentor new advocates.

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1na4lvPK7hokh/bibliography/public/