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: Research Specialist, Research Cancer Advocate

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's of Science degree in biology/microbiology and extensive laboratory experience in molecular biology. I am also a 16-year survivor of breast 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 a 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 into 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. Therefore I am uniquely qualified to serve on the External Advisory Board of the Johns Hopkins SPORE in Breast Cancer.

Spears, P.A. 2002. Breast cancer prevention through the eyes of a survivor. Environ. Mol. Mutagen. 39:108-111. [PMID: 11921177]

Spears P.A. 2011. Phase 0 Clinical Trials: Taking Advantage of a "Window of Opportunity" in Breast Cancer. Breast Disease Quarterly. 22(3):252-4. [http://dx.doi.org/10.1016/j.breastdis.2011.06.054]

Shapira I., T. Deshields, D. Kroetz, P. Friedman, **P. Spears**, D. Collyar, L. N. Shulman, M. M. Bertagnolli, L. Dressler and J. Peppercorn. 2012. Ethical Aspects of Participation in the Database of Genotypes and Phenotypes (dbGaP) of the National Center for Biotechnology Information (NCBI): The CALGB experience. Cancer. Oct 15;118(20):5060-8. [PMID: 22415847]

Wolff, A.C., M.E.H. Hammond, D.G. Hicks, M. Dowsett, D.C. Allred, J.M.S. Bartlett, M. Bilous, P. Fitzgibbons, W. Hanna, R.B. Jenkins, P.B. Mangu, L.M. McShane, S. Paik, E.A. Perez, M.F. Press, **P.A. Spears**, G.H. Vance, G. Viale and D.F. Hayes. 2013. Recommendations for Human Epidermal Growth Factor Receptor Testing in Breast Cancer: American Society of Clinical Oncology - College of American Pathologists (ASCO/CAP) Clinical Practice Guideline Update. J. of Clin. Oncol. J Clin Oncol. 2013 Nov 1;31(31):3997-4013. [PMID: 24101045]

B. Positions and Honors

Positions and Employment

1984-1986 Research Technician III, North Carolina State University, Coll. of Vet. Med
1986-1987 Research Assistant II, Harvard Medical School
1987-1990 Research Assistant, Brown University
1991-1992 Research Associate I, Becton Dickinson Research Center

1992-1994	Research Associate II, Becton Dickinson Research Center
1994-1997	Scientist, Becton Dickinson Research Center
1997-2001	Research Scientist, North Carolina State University, Coll. of Vet. Med.
2001-2007	Research Technician III, North Carolina State University, Coll. of Vet. Med
2007-Present	Research Specialist, Advanced, North Carolina State University, Coll. of Vet. Med.

Other Professional Affiliations, Teaching, Honors and Trainings

Professional Affiliations

1992-present American Society for Microbiology

Teaching

2008-2010	Lecturer, Senior Rotation in Microbiology VMP977
2006-present	Laboratory Teaching Assistant, Pathogenic Bacteriology and Mycology, VMP914/910
2008-2012	Guest Laboratory Lecture, Pathogenic Bacteriology and Mycology VMP914, Molecular Diagnostic Microbiology
2013-present	Laboratory Teaching Assistant, Problem Solving Cases Infectious Disease & Immunity 2, VMP934
2013-present	Duke Cancer Institute, Translational Aspects of Pathobiology, Patients Advocates in Research

Honors

2002	Susan G. Komen, New Volunteer of the Year Award
2003	Susan G. Komen NC Triangle Affiliate, Maureen Jordan-Thomas Spirit of Survivorship Award
2007	National Cancer Institute, caBIG™ Patient Advocate Award
2013	North Carolina State University, College of Veterinary Medicine, Award for Excellence
2010-present	Susan G. Komen for the Cure, Komen Scholar, Advocate Member

Cancer Advocacy Trainings

2003	National Breast Cancer Coalition, Project LEAD® Graduate
2007	American Association for Cancer Research, Scientist<->Survivor Program participant
2012	The Cochrane Collaboration, Understanding Evidence Based Healthcare: A Foundation for Action
2013	National Institutes of Health, Protection of Human Research Participants Certificate
2014	Research Advocacy Network, Focus on Research at ASCO Breast Cancer Symposium
2014	San Antonio Breast Cancer Symposium, Alamo Breast Cancer Foundation, Scholarship Recipient

C. Contributions to Science/Advocacy

1. I have contributed to the conduct of clinical trials from the local level at 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) where I initiated a high standard for myself and future advocates on the BCSC. The significance of my contributions is to bring the patient voice to the development of National Clinical Trials Network 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.

    a. The Alliance for Clinical Trials in Oncology. The Alliance is one of the five National Clinical Trials Network groups, which resulted from the merging of three groups including CALGB. I have been involved with CALGB since 2008 and am now co-Chair of the Patient Advocate Committee, serve on the Board of Trustees, am a member of the Data Safety and Monitoring Board of the Alliance. I am also a member of the Breast Cancer, Prevention and Ethics committees. I recently published an article in the Alliance Newsletter on accrual

(https://www.allianceforclinicaltrialsinoncology.org/main/cmsfile?cmsPath=/Public/Newsletters/files/Summer-Vol-5-No-3-2015.pdf)

b. Duke Cancer Institute. I have been a member of the Cancer Protocol Committee since 2005, where I review consent forms for content and readability. Since 2014 I have been a member of the External Advisory Committee of the Clinical and Translational Science Award (CTSA), where I contribute to all clinical trial activities at Duke.
c. National Cancer Institute. I served on the inaugural Breast Cancer Steering Committee from 2009 until 2013, where I initiated the role of the advocate to be integrated so the patient perspective was documented in writing as well as spoken during the review. I am currently serving on the new Core Correlative Science Committee and the Network Accrual Core Team, both initiated after the reorganization of the NCTN.
d. Translational Breast Cancer Research Consortium. I served as the Duke representative to the TBCRC from 2008 until 2013. I was a member of the Patient Advocate Committee as well as the HER2 resistance committee. In my role as advocate I interacted with researchers from all member institutions including Dr. Vered Stearns at John's Hopkins.

2. I have participated in multiple panels and review committees sponsored by various organizations including 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) 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 recently joined the guideline panel for post mastectomy radiotherapy, which will result in a publication and guidance in this critical area of patient care.

    a. ASCO Guideline Panels. I have had the opportunity to participate on two pivotal panels in breast cancer. In 2012 to 2013 I was 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 content (http://www.cancer.net/sites/cancer.net/files/her2-testing_infographic_large.pdf), which I contributed to the final design. I am currently participating in the ASCO Post Mastectomy Radiotherapy (PMRT) Guideline Panel.
    b. FDA Panels. I have had the opportunity to participate in two FDA panels of significance. In 2013 I was a panel member of Innovations in Breast Cancer Drug Development, Neoadjuvant Breast Cancer Workshop. The outcome and open discussion at this workshop was the basis for early approval of pertuzumab based on neoadjuvant data, which accelerated its use in patients. In 2014 I was a panel member of Innovations in Breast Cancer Drug Development, Next Generation Oncology Trials, Breast Cancer Workshop, which was a pivotal discussion to push forward gnomically driven trials in metastatic breast cancer.
    c. Friends of Cancer Research (FOCR). In 2011 I participated in the Conference on Clinical Cancer Research on the panel for Evidence for Use of Maintenance Therapy. This resulted in a summary publication (http://www.focr.org/sites/default/files/Panel2FINAL110111.pdf). I am currently planning to participate in the 2015 meeting on a panel addressing the use of Patient Reported Outcomes in Clinical Trials, which is another area I have been involved with this past year.

3. I have had the opportunity to work on key research projects including the Breast Cancer SPOREs and Department of Defense projects. Being involved with research at Duke Cancer Institute and John's Hopkins Sidney Kimmel Comprehensive Cancer Center have 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. I also contribute to the conduct of the first-in-human clinical trials, which involves many patient related issues and concerns. I participate in bi-weekly meetings and present the advocate perspective of the two DOD projects during external advisory committee meetings.

    a. Duke's Department of Defense Research Projects. 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. The PI of both is Dr. H. Kim Lyerly. I have been attending regular meetings and reviewing information as needed. There has been a tissue acquisition protocol

initiated that will benefit both projects. There are also first-in-human studies that will be initiated in both studies within the next year.

b. NCI SPORE programs. I began research advocacy as a patient advocate on the Duke Breast Cancer SPORE program from 2005 until 2009. During that time I got to know all the SPORE projects and their Principal Investigators. I also met with the advocates of other SPOREs and joined the Patient Advocate Team as an Advisory Committee member. Through this group I helped develop and deliver SPORE advocate trainings at the annual meetings. This interaction provided the basis of what I can bring to the John's Hopkins Sidney Kimmel CCC Breast Cancer SPORE as an external advisor. I have been working with Dr. Vered Stearns and other John's Hopkins researchers since 2013 supplying input on potential projects.

c. PCORI project. I have been involved as one of the key advocates on a PCORI project titled "Post-treatment surveillance in breast cancer: Bringing CER to the Alliance". I have provided input during grant submission, regular meetings and teleconferences. In the fall of 2015 I will co-present an update on the project at the first 2015 PCORI Annual Meeting with Dr. Caprice Greenberg, Principal Investigator of the project.

4. I have been involved in many educational activities providing the development or delivery of trainings and scientific information to the public and advocates. I enjoy developing written materials as well as speaking in public arenas about patients, advocacy and clinical trials.

   a. Cancer Support Community. In 2013 I served on the Immuno-Oncology Advisory Board where I helped create an information document on cancer immunotherapy that is available to the public at http://www.cancersupportcommunity.org/General-Documents-Category/Education/Frankly-Speaking-About-Cancer-Your-Immune-System-Cancer-Treatment-Fact-Sheet.pdf. In 2014 I participated in the Voice America, Frankly Speaking About Cancer, Your Immune System and Cancer Treatment where I was a participant in a radio broadcast on cancer immunotherapy.

   b. National Meeting Presentations. 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.* It is important to encourage and inspire surgeons to accrue to clinical trials. 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 http://webcast.aacr.org/console/player/27566?mediaType=audio&. Prior to the conference I conducted a survey of advocates on their thoughts about PROs in clinical trials and presented those results. It is important to provide a broad patient advocate viewpoint.

   c. Accelerating Anticancer Agent Development and Validation Workshop. In 2015 I participated as a planning committee member. My contributions included identifying a topic for one of the discussion groups and co-chairing that discussion group. I helped supply speakers and organize the presentations. I am also an active participant of Komen's Advocates in Science and helped to develop an advocate training program prior to the AAADV Workshop which was called Working Together. This provided extra education for advocates prior to participating in the full Workshop.

   d. Cancer Information and Support Network. I am a consultant for CISN and have been involved in several educational activities. I helped develop the content for the CISN Research Advocacy websites at http://cisncancer.org/advocacy/research_advocacy.html. I am also assisting with NCTN Advocate Training, which is a series of webinars. I am assisting with content and will be delivering the webinar titled Clinical Trials 201 in August 2015.

5. I have been an advocate reviewer of research grants since 2003 and I continue to participate in grant reviews for Susan G. Komen (SGK) and Patient Centered Outcomes Research Institute (PCORI). 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 am also heavily involved in the grants committee at SGK through my participation on the Advocates in Science (AIS) Steering Committee.

   a. Susan G. Komen. I have been reviewing grant applications as an advocate reviewer for Komen since 2003. There have been a lot of changes in those years. The program is overseen by Komen Staff as well as Komen Advocates in Science, leadership community. I have been involved in many aspects including mentoring, training and assessment of advocate reviewers in peer review.

b. PCORI. I have reviewed research grant application for the Assessment of Prevention, Diagnosis and Treatment Options (APDTO) Panel for 3 cycles since 2013 as a stakeholder reviewer. This experience allows me to know more about PCORI grant applications.
c. Department of Defense. From 2005 until 2007 I participated in peer review for the Congressionally Directed Medical Research Program (CDMRP) in Breast cancer as a consumer reviewer. Even though I have not reviewed for them in a while, the experience it afforded me carries through my current review opportunities.

Complete List of Published Work in My Bibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/1na4lvPK7hokh/bibliograpahy/48358627/public/?sort=date&direction=ascending

D. Research Support
N/A