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:

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

POSITION TITLE:

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

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role as an advocate in the project described in this application. The relevant factors may include aspects of your advocacy training; your previous work on this specific topic or related topics, your previous relationship to these researchers; and your past experience in this or related fields (you may mention specific contributions to advocacy that are not included in Section C).

Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project.

B. Positions and Honors

Positions and Employment:

- List in chronological order previous positions, concluding with the present position.
- This is your work experience if applicable, any employment. There is a lot of information in someone's past experience.

Honors/Awards

- List any honors or awards in your professional or advocacy work. Include present membership on any Federal Government public advisory committee.

You can also list other headings if you think it would strengthen your application.
For example:
Cancer Advocacy Training
Professional/Advocate Experience and Membership

C. Contribution to Advocacy and/or Science

- Briefly describe up to five of your most significant contributions to advocacy and/or science. For each contribution, indicate the historical background that frames the contribution; and your specific role in the described work.

- For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution.
- The description of each contribution should be no longer than one half page including figures and citations.
- Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine. You can use this link to set up your bio-database https://www.ncbi.nlm.nih.gov/account/?back_url=http%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed

D. Research Support

- Put N/A if you are not funded by an ongoing research project or one ended in the past 3 years.
- List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported).
- *Begin with the projects that are most relevant to the research proposed in the application.*
- Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

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: Smith, Jane

eRA COMMONS USER NAME (credential, e.g., agency login): jsmith NOTE: if you don't have one, leave blank

POSITION TITLE: Cancer Research Advocate NOTE: or a variation of your choice.

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 California, Berkeley NOTE: List all degrees, relevant or not	B.S.	05/1984	Plant Biology

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 plant biology and extensive laboratory experience in this field. 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 a clinical trial) 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 as the patient advocate on this research project that will be studying environmental factors in breast cancer development.

NOTE: If you have advocacy, breast cancer or other articles that you would like to cite, list up to 4 here.

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

Smith, J. 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]

B. Positions and Honors

Positions and Employment

1984-1995 Assistant, Major Company, Hometown, MD
1995-2007 Manager, Major Company, Hometown, MD
2007-present Assistant Director, Major Company, Hometown, MD
2014 -present Consultant, Major non-profit Institution, Anywhere, PA

Other Experience and Professional Memberships

1984-present Member, American Association of Plant Biologists
2010-present Advocate Member, American Association of Clinical Oncology

Honors

2007 Susan G. Komen, New Volunteer of the Year Award

2009 Susan G. Komen NC Triangle Affiliate, Maureen Jordan-Thomas Spirit of Survivorship Award
2011 National Cancer Institute, Special Patient Advocate Award
2013 Major Company, Employee Award for Excellence

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. Contribution to Advocacy and/or Science

NOTE: Here is where you can take advantage of telling the reader the general areas you focus on for advocacy and then list accomplishments in those areas. You can highlight up to 5 area.

For example, the first area on this biosketch is clinical trials. Write a general statement about your ideas on contributions, then list the different organizations/committees etc. that further support this area of advocacy.

1. I have contributed to the conduct of clinical trials from the local level at Local Cancer Institute to the National level as an National Clinical Trials Network advocate. I served as the inaugural patient advocate member of the National Cancer Institute's XX Steering Committee (XXSC) where I initiated a high standard for myself and future advocates on the XXSC. 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. National Clinical Trial Group. The NCTN group is one of the five National Clinical Trials Network groups, which resulted from the merging of three groups. I have been involved with NCTN group 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 NCTN group. I am also a member of the Breast Cancer, Prevention and Ethics committees. I recently published an article in the NCTN group Newsletter on accrual (**Link here to article**)
    b. Local 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 Local Cancer Institute.
    c. National Cancer Institute. I served on the inaugural XX 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 Local Cancer Institution 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. Jones at Cancer Institute. (NOTE: If you can link an experience to the applicant, it would be good)

NOTE: This next area is as an advocate on special committees that were important and where products were produced.

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 (***link to website content***), 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 (***link to meeting summary document***). 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.

NOTE: This section is highlighting activity as an advocate on several research grants. If this is biosketch is being submitted for a research grant you really want to highlight your previous activity as well as your contribution.

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 The XX Cancer Institute and the XX 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. Institution Department of Defense Research Projects. Since 2012 I have been involved in two Department of Defense funded projects at Institution, a Transformative Vision Award and a Clinical Translational Research Award. The PI of both is Dr. Jones. 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 Institution 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 Institution CCC Breast Cancer SPORE as an external advisor. I have been working with Dr. Kelly and other Institution researchers since 2013 supplying input on potential projects. (NOTE: mentioned to link to the proposal being submitted)
c. PCORI project. I have been involved as one of the key advocates on a PCORI project titled "Developing patient centered breast cancer decision making and bringing it to the patient". 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. Black, Principal Investigator of the project.

NOTE: This next section highlights any education activities you have participated in, as an organizer, speaker, local or nationally.

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 ***link to published document***. 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 ***link to webcast***. 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 ***link to website content***. 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.

NOTE: This section is all about being an advocate/consumer reviewer. This is where you can describe in general why and what you do and then give up to 4 specific examples.

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:

NOTE: If you have peer reviewed published articles go to https://www.ncbi.nlm.nih.gov/account/?back_url=http%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed to create a list of your published articles. Paste the link here.

Link to published articles

D. Research Support
N/A

NOTE: Or if you have grant support as a PI, co-PI or Collaborator, list it here.