Roadmap to Research Advocacy in Translational Sciences

Research Advocacy Network
Advancing Patient-Focused Research

Research Advocacy Network

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Roadmap to Research Advocacy in Translational Science

Advocating for the advancement of research is crucial to finding new and better treatments for cancer patients. Cancer survivors, their caregivers and families are uniquely positioned to support cancer research in new and innovative ways. If you are a cancer survivor, caregiver or family member, you may find the following Q & A helpful in exploring this new and dynamic way that you can help cancer patients now and in the future.

What is research advocacy?

Research advocacy infuses the patient perspective into research making scientific and medical advances more timely and effective for people with cancer. Research advocates help provide a "face" to the science – as researchers focus on new approaches to cancer treatment, research advocates work alongside them and remind them of the human element. This partnership ensures clinical trials ask questions important to patients, eligibility criteria allow diversity of participation, and trial designs attract potential participants. Research advocates support conducting ethical, well-designed research and work to disseminate the results of that research so that new and better treatments are available in communities throughout the United States.

What have research advocates done to support research?

Research advocates support research by enhancing clinical trial/study design. They review protocols, serve on study sections and conduct or participate in focus groups providing input into specific trial designs.

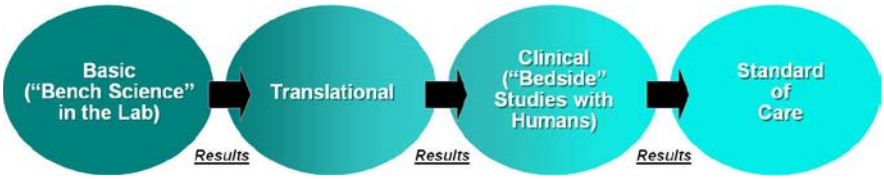
Research advocates serve on Institutional Review Boards (IRB) at academic medical centers and their local hospitals. Research conducted at an institution that is federally funded must have IRB approval. Each IRB is required to have a voting member from outside the institution and is not affiliated with the institution. This person serves as a community member and provides the perspective of his or her community to the board's discussions.

Research advocates review proposals for research projects. These advocates work with the scientific panel to prioritize and decide which proposals will be funded based on merit. For example, the Department of Defense Cancer Research Program and the Susan G. Komen for the Cure include research advocates on their review panels.

Research advocates participate in formal programs sponsored by the federal government. These federal agencies include the National Cancer Institute's CARRA (Cancer Advocates in Research and Related Activities) and Director's Consumer Liaison Group, the Food and Drug Administration's consultant program and the Institute of Medicine (IOM) panels.

What is Translational Research in Oncology?

To improve human health, scientific discoveries must be translated into practical applications. Such discoveries typically begin at "the bench" where basic researchers study disease at a molecular or cellular level then progress to the clinical level, or the patient's "bedside."



Source: Research Advocacy Network

Scientists are increasingly aware that this bench-to-bedside approach to translational research is really a two-way street. Basic scientists provide clinicians with new tools for use with patients and for assessment of their impact, and clinicians make novel observations about the nature and progression of disease that often stimulate basic investigations.[1]

The National Cancer Institute's Translational Research Working Group (TRWG) defines Translational Research in the following way: "Translational research transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce cancer incidence, morbidity, and mortality."

Who conducts "Translational Research"

Translational research will most often be conducted at an academic center by MDs or PhDs. Professionals from many disciplines including bioinformatics, statisticians, and epidemiologist are part of the translational research team. Much of the translational research occurs at academic medical centers rather than community sites.

Importance of the advocate perspective in translational research

Since translational researchers many times don't have direct patient contact, it is very important for advocates to have the opportunity to interact and provide the patient perspective. Another challenge is that because of the nature of translational research it may also be more difficult for the translational research team to identify advocates and to know how to integrate the patient perspective in a meaningful way.

[1] http://commonfund.nih.gov/clinicalresearch/overview-translational.aspx accessed 3/19/2011

What does the translational research team look for in an advocate?

- Someone with a passion to advance research
- Someone with a history with the disease
- Someone who can express ideas clearly
- Someone who uses a collaborative approach

Making the connection:

At a meeting with the PI of the project/aim you might ask:

- What is your vision for how your research will help people?
- What patient population(s) are you targeting?
- What outcomes do you expect from your research?
- What type of clinical trial will you propose to reach that outcome in the clinic?
- How long do you project it will take to move the science out of the lab and into the clinic?

You may suggest some ways to the researcher to begin to work together toward the goals identified in your meeting. These methods may include:

- Educating advocates on the science being conducted. Some methods to educate the advocates include:
  - Finding out if there are any existing resources - printed or electronic
  - Conducting a symposium for advocates
  - Holding web conferences
  - Developing written materials
- Assist in preparation for clinical trial(s) by:
  - Testing the proposed trial design with surveys, focus groups, structured interviews to test trial design and or elements of the trial such as randomization, method of drug delivery, side effects, duration of treatment, questionnaires, procedures, e.g., tissue biopsy
  - Better understanding the patient population to be studied and motivation for messages, patient education materials
  - Testing patient education materials
  - Developing provider information (10 tips on presenting the information to patients, answers to questions in a brochure, talking points, scripts)
- Increase clinical trial awareness
  - increase awareness of community about new research and clinical trials
  - increase awareness about specific research and/or clinical trials, e.g., vaccine trials or specific vaccine trial being conducted
  - develop materials for community providers about type of research and/or specific trial(s)

- Hold tissue awareness events in the community
- Conduct research on patient decision-making regarding clinical trials
    - provider behaviors
    - patient behaviors
- Develop a publication in lay language of research results and dissemination of those results to the community

Opportunities for Research Advocates in Translational Research

Opportunities for advocates to be "at the table" when research is being discussed and planned has increased over the past decade. This is due in large part to volunteers being available, vocal and efficient in providing the patient perspective to the research process. In each interaction and opportunity, the individual has a tremendous responsibility to make the most of the experience by being prepared and engaged. We have listed a few opportunities to help get you started. This is not an exhaustive list. Help us add to these opportunities as you find new and creative ways to advocate in research. These opportunities can be submitted via email to info@researchadvocacy.org. Additional opportunities may be listed on our web site at www.researchadvocacy.org.

Advocate Review of Translational Research Proposals

Being a research advocate offers a unique opportunity to actively bring the patient perspective to the researchers as they develop their concepts and protocols. While each of us has individual perspectives to share, it is useful to have a format within which to work, to help us to organize our input in an effective way that is meaningful to the researchers.

Start by looking at the Aims or Hypothesis. Is the question(s) they are seeking to answer 1) important to patients with cancer and 2) is this an unmet need for the patient population they are studying?

When looking at evaluating the proposed research here are some things to consider:

- Is this the best patient population to study? Should other populations be considered?
- Access issues for future patients
  Is the technology or equipment being used widely available so that if the results positively affect patient care, the treatment would be widely available?
- Cost issues for participants and future patients
  Have the investigators assessed the cost for patients participating in the research?
  Have the investigators assessed the cost to future patients?
- Can the activities be completed in the one year or two year time frame of the grant? If not, what is the plan for completion without this funding?
- Have patient needs and concerns been adequately addressed?

Does the application discuss the issue from the patient viewpoint, e.g., fear of recurrence, pain, functioning and quality of life, and how the new approach would affect their quality of life as well as the effectiveness of treatment?

- If a trial is being proposed, are the tests and procedures acceptable to this patient population? Is there anything you can suggest to make the study more acceptable or attractive to patients?
- Suggest adding patient reported outcomes to Phase II trials (We can offer talking points on this topic if you think that would be helpful.)
- Ask about the toxicity of a new drug when used with a chemotherapy regimen or targeted therapy – does it increase the toxicities of the regimen, decrease the toxicities or not affect toxicities
- Check NCCN guidelines if you have questions about current standard of care

SPORE Patient Advocates	
Description of opportunity:	Patient advocates that are willing to focus their attention on helping the NCI-funded Specialized Program of Research Excellence (SPORE) research programs translate their research into practical use for people. There are 52 SPORE programs in specific diseases (brain, breast, colon, GI, GU, gynecologic, head & neck, leukemia, lung, lymphoma, myeloma, ovarian, pancreas, prostate, skin) located in academic institutions throughout the U.S. These SPOREs connect many disciplines, including basic, epidemiological, and clinical scientists, together to plan, design and implement research programs that have an impact on cancer prevention, detection, diagnosis, treatment and control. SPORE Patient Advocates can become involved in many opportunities, depending on what the needs of their particular SPORE are, and the interest of each patient advocate. Some of the opportunities may include: [2] • Attend and participate in research discussions and strategy meetings • Hold 2-way educational sessions for patient and research communities • Brainstorm on ways to improve the clinical trial system for participants • Help identify barriers that keep SPORE research from moving forward, and participate in steps to resolve these issues • Learn why tissue is important to researchers and patients, and help researchers get more of what they need while respecting privacy issues • Give input into clinical trial development and design

[2] Source: http://spores.nci.nih.gov/part/index_part.html#feedback downloaded 3/ 4/2008

SPORE Patient Advocates	
	• Help review small, "seed" grants that SPOREs can fund • Help spread the word about SPORE clinical trials in a variety of ways SPORE Advocates also have: • Written copy for web sites, newsletters and blogs • Reviewed annual progress reports required by the National Cancer Institute • Represented their SPORE at scientific conferences such as the National Cancer Institute Translational Science Meeting For a listing of current SPOREs by state location: http://spores.nci.nih.gov/spores/bystate.htm For a listing of current SPOREs by organ disease site: http://spores.nci.nih.gov/spores/bylocation.htm
Travel Required	Travel to meeting location
Time required:	Program/ assignment dependent
Skills:	• Patient-focused approach • Willing to make a personal commitment to work directly with cancer researchers within a local SPORE program. • Basic understanding of scientific process / cancer being studied • Good communication skills both verbal and written • Critical thinking skills to formulate questions and respectful, confident approach to ask questions
Training offered:	Program dependent
Compensation / Expenses	Usually volunteer Out of pocket (parking, etc.) may be reimbursed.
Resources:	• http://spores.nci.nih.gov/ • Educational materials on Tissue and Biospecimen Donation for Research Purposes www.researchadvocacy.org • Genomics in Cancer Research www.researchadvocacy.org • Clinical Trial Design www.researchadvocacy.org
Opportunity contacts:	• http://spores.nci.nih.gov/ • Staff or volunteers at SPORES at academic medical centers listed above and on the SPORE website • Clinicians/Researchers at academic medical centers as well as SPORE PI's.

Site Program Advocates

Description of opportunity:	Many funding organizations now make it a condition of funding that advocates are involved in meaningful ways in the implementation of the scientific aims of the project.
	
	Advocates could be involved in many facets of the research project, including identification of the research question, project design, oversight, recruitment, and evaluation, in addition to other areas. Interactions with the research team members should be well-integrated and ongoing, not limited to attending seminars and semi-annual meetings. Some meaningful ways for advocate involvement include:
	
	• Review the proposed design of a clinical trial
	• Provide guidance from the point of view of a cancer patient (potential participant in the research) with regard to eligibility, frequency of invasive testing, etc.
	• Assist in developing the approach for patient accrual through messaging and community outreach, such as:
	  o Creating patient education materials to explain the research project and clinical trial and how the trial might be an option for patients
	  o Working with community organizations to inform and engage cancer patients in the trial
	  o Monitoring patient accrual and, if needed, suggest modifications to the approach
	  o Monitoring the patient experience, such as through development of a questionnaire or personal interview, and providing assistance and support when necessary
	  o Reviewing the language contained in Informed Consent forms, questionnaires, and other documents related to patient involvement for readability and sensitivity
	• Assist in the development of the lay abstract for publication or presentation.
	• Help develop an educational approach for local, regional, and national groups and organizations to inform them of the research being conducted and why it is important to cancer patients through community events, web conferences, and written materials they can use on their web sites and in their newsletters.
	• Speaking as part of the research team at scientific meetings and conferences to present the impact of the work to the cancer patient
	• Preparing and delivering a poster presentation for scientific meetings and conferences, for instance, on the approach to patient accrual
	• Developing an educational approach for patients to explain how the results could be an option for their treatment.
	• Speaking in the community about the results of the research. This is best done as a team with a researcher and an advocate making the presentation.

Site Program Advocates	
	• Being included as an author on a publication if appropriate (This section was adapted from Susan G. Komen for the Cure Promise Grant RFA 2010- Appendix A) Examples: • Congressionally Directed Medical Research Program - Dept of Defense (DOD) Grants • Komen Promise Grants • NCI Clinical Proteomic Technologies for Cancer (CPTAC)
Travel Required	Program/ assignment dependent
Time required:	Program/ assignment dependent
Skills:	• Patient-focused approach • Willing to make a personal commitment to work directly with cancer researchers • Basic understanding of scientific process / cancer being studied • Good communication skills both verbal and written • Critical thinking skills to formulate questions and respectful, confident approach to asking questions
Training offered:	Program dependent
Compensation / Expenses	Usually volunteer Out of pocket (parking, etc.) may be reimbursed.
Resources:	Genomics in Cancer Research www.researchadvocacy.org Clinical Trial Design www.researchadvocacy.org
Opportunity contacts:	• CDMRP (DOD) Grants Peer Reviewed Cancer http://cdmrp.army.mil/prcrp/default.shtml • Komen Promise Grants http://ww5.komen.org/ResearchGrants/FundingOpportunities.html • NCI Clinical Proteomic Technologies for Cancer (CPTAC) http://proteomics.cancer.gov/about/

Grant review	
Description of opportunity:	Consumers participate in the scientific review process as representatives of the disease that has touched their lives. Advocates offer the patient perspective on applications for grant funding from the scientific community. Agencies that involve consumers (or advocates) set the parameters of review and method. Applications usually involve basic, translational or clinical research and can include quality of life, psychosocial needs and ethical issues. Agencies offering consumer/advocate review positions: • Dept of Defense Congressionally Directed Medical Research (CDMRP) (Currently funding programs in Breast, Lung, Ovarian, and Prostate Cancer) • Susan G. Komen for the Cure (Breast Cancer) • National Lung Cancer Partnership (Lung Cancer)
Time required:	Varies - Dependent on agency and volume of proposals expected to review
Travel required:	Possible
Equipment:	• If review is to be done online, internet access • Fax availability is helpful • If conference calls are involved it is helpful to have a headset for a land line phone so you can be hands free to make notes. Cell phones are not the best method for conference calls as calls may be dropped and background noise may be distracting.
Skills:	• Basic understanding of scientific process / disease or condition being studied • Good communication skills both verbal and written • Critical thinking skills to formulate questions and respectful, confident approach to ask questions • Ability to assess merits of the project • Understanding of scoring guidelines and agency expectations • Ability to balance tenacity and flexibility
Training offered:	• Program dependent

Site Program Advocates

Resources:	• Medical Dictionary, Encyclopedia, some tutorials http://medlineplus.gov/ • NCI Consumer Guide to Peer Review http://deainfo.nci.nih.gov/PeerReview/GuideCompleteBook.pdf • NCI Consumers' Cancer Dictionary for Peer Review http://deainfo.nci.nih.gov/PeerReview/DictionaryCompleteBook.pdf • Oncology Nursing Society Continuing Education Series Online Cancer Biology ($40 non ONS member registration fee) http://onsopcontent.ons.org/Education/DistanceEducation/CancerBiology/index.shtml • Oncology Nursing Society Continuing Education Series Online Cancer Basics ($80 non ONS member registration) http://onsopcontent.ons.org/education/distanceeducation/cancerbasics/
Opportunity contacts:	• Department of Defense Medical Research Program (CDMRP) Consumer Involvement http://cdmrp.army.mil/cwg/default.shtml Questions concerning consumer involvement can be addressed to the Congressionally Directed Medical Research Programs at: ATTN: Consumer Recruitment 1077 Patchel Street Fort Detrick, MD 21702-5024 Phone: 301-619-7071 Fax: 301-619-7796 E-Mail: cdmrpconsumers@amedd.army.mil • National Cancer Institute Contact the Office of Advocacy Relations at Email: nciadvocacy@mail.nih.gov Phone: (301) 594-3194 • (Breast Cancer) Susan G. Komen for the Cure Advocates in Science information http://ww5.komen.org/ResearchGrants/KomenAdvocatesinScience.html or send email to advocatesinscience@komen.org. • (Lung Cancer) National Lung Cancer Partnership 222 N. Midvale Blvd., Suite 6, Madison, WI 53705 Phone: 608.233.7905 Fax: 608.233.7893 E-mail: info@NationalLungCancerPartnership.org www.NationalLungCancerPartnership.org

Public Comment on Regulatory Issues	
Description of opportunity:	When federal regulations are proposed there is often a window of time when the regulations are posted for public comment. This is a great time to have your voice heard on issues that are important to advancing research and better patient care. For example: The U.S. Preventive Services Task Force (USPSTF) invited public comment on its draft Recommendation Statements before they were published. Testicular cancer screening and bladder cancer screening were two topics offered for public comment in 2010.
Travel Required	Not usually – comments usually submitted online
Time required:	Variable
Skills:	Good written communication skills Appraisal and critical thinking
Training offered:	Self study Appraisal and critical thinking : Advocate Institute course
Compensation/Expenses	N/A
Resources:	• Federal Register listing of open comments for Health and Public Welfare http://www.federalregister.gov/health-and-public-welfare#comment-period-opening • Regulations.gov(Search on key terms to find notices and regulations open for public comment) www.regulations.gov • NCI Office of Advocacy Relations - maintains a listing of cancer related federal policies that are open for public comment http://advocacy.cancer.gov/activities/comment • AHRQ Effective Health Care research available for comment http://effectivehealthcare.ahrq.gov/index.cfm/research-available-for-comment/
Opportunity contacts:	(see resources)

Steering Committees and Advisory Boards	
Description of opportunity:	Many sites and divisions of the NIH and NCI have steering committees, advisory boards and special panels. For example: NCI has the Director's Consumer Liaison Group (DCLG), NIH has the Council of Public Representatives (COPR)
Travel Required	Dependent on assignment
Time required:	Variable
Skills:	Good communication skills Foundational knowledge of cancer research
Training offered:	Orientation to the committee may be offered but formal training is usually not For information about Research Processes and Basic Knowledge: Advocate Institute www.researchadvocacy.org or www.advocateinstitute.org Project LEAD (Breast Cancer) http://www.breastcancerdeadline2020.org/learn/project-lead/ AACR Scientist Survivor http://www.aacr.org/home/survivors--advocates/scientistharr;survivor-program.aspx
Compensation/Expenses	Dependent on assignment – honorariums are sometimes offered
Opportunity contacts:	NCI Office of Advocacy Relations - http://advocacy.cancer.gov/activities/applications