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## New and Improved: The NCI's Best Case Series Program Now Designated As a Protocol

A patient with cancer who has exhausted commonly prescribed options may have a treatment suggested to them by their doctor that is not traditionally indicated for cancer. The patient agrees to the therapy, takes it, and finds themselves significantly better, or even cured. Although the doctor thinks he may have a promising treatment on his hands, he most likely does not have the resources available to conduct a large clinical trial or engage in laboratory research. What can he do next? He can submit case reports of these patients to the NCI Best Case Series (BCS) Program, which has recently been approved as a protocol. This long-standing program was initially developed in 1991 in response to an evaluation by the Office of Technology Assessment (OTA), per request by the United States Congress. From 1991-1997, it was overseen by the NCI's Cancer Therapy Evaluation Program of the Division of Cancer Treatment, Diagnosis, and Centers (DCTC). The objective was to assess cases that used alternative regimens to treat cancer and determine if there was enough evidence for NCI to support more research of the treatment, such as the initiation of a clinical trial. With the establishment of NCI's Office of Cancer Complementary and Alternative Medicine (OCCAM) in 1998, management of the program was transferred. Currently, it is under the direction of the Case Review and Intramural Science Program (CRISP) of the OCCAM. The Director of CRISP is Dr. Farah Zia and the CRISP Coordinator is Dr. Oluwadamilola Olaku. Dr. Zia is the Principal Investigator of the NCI BCS Program.

After a recent review by the Office for Human Research Protections, the NCI BCS Program was determined to meet criteria for clinical research. This led to the development of a written protocol which subsequently was reviewed and approved by NCI's Special Studies Institutional Review Board. The protocol describes in detail the processes and procedures involved in the selection and evaluation of cases for review. The change to a protocol may make publishing case reviews easier because Dr. Zia notes, "Journal reviewers will know that the protocol used to review the cases achieved ethics clearance."



*From left to right: Cancer Research Training Award fellow Jeans Santana, Dr. Farah Zia, and Dr. Oluwadamilola Olaku discuss the NCI Best Case Series.*

Although there is no change to submission criteria, under the protocol there are now "eligibility" criteria. According to Dr. Zia, "As with all protocols, these criteria are established to ensure that the results of the research are reliable."

Under the new protocol, the investigators will provide the CAM practitioner with a "mini-consent" form to document that a patient, whose medical case history is

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being considered for submission, agrees to the release of their basic contact information (e.g., name, telephone number) to OCCAM. Once OCCAM receives this “mini-consent” one of the BCS investigators will contact the patient asking for their written consent to have their identified medical records reviewed as part of the study. This step is an important requirement for the new protocol — it ensures that all of the patients receive accurate and consistent information regarding the Program (as opposed to just receiving information from their doctor) and it makes clear that their medical records will be viewed by different people associated with the program (including the BCS investigators, pathologists, radiologists, and external reviewers).

Despite the fact that patients involved in this research have already completed treatment, their participation is extremely valuable. Dr. Zia comments that when patients provide consent to participate in the study, “they are helping to contribute to the evidence for a specific cancer CAM treatment. If this leads to the development of a new, approved therapy, future patients would benefit.”

Analysis of case reports takes place in two parts: a pre-research assessment and a comprehensive review. Practitioners initially submit a de-identified summary of each case planned for submission, which is reviewed for eligibility to the Program. The summaries describe the treatment and are used to determine that the patients had a diagnosis of cancer by tissue biopsy, that there is detectable disease on radiographic imaging prior to the start of the unconventional regimen, and that conventional therapies were not used alongside or within 4 weeks of the unconventional therapy. Once cases that meet eligibility criteria are identified, BCS investigators obtain patient consent and request their complete medical records from the submitting practitioners. Under the new protocol requirements, practitioners may send a minimum of 3 and up to 20 case reports to be reviewed. However, if CAM



*CRISP staff review radiographs submitted to the NCI Best Case Series.*

practitioners only have one or two cases available, they are encouraged to contact CRISP. While one or two cases are not enough to be eligible for a full review, the CRISP staff may be able to provide some feedback to the practitioners.

During the comprehensive review, the medical records, pathology slides, and radiographs are carefully examined by BCS investigators, along with pathologists and radiologists from the NIH Clinical Center (the NCI Laboratory of Surgical Pathology and the NIH Diagnostic Radiology Department). Following this review, the cases are rated as “Persuasive,” “Supportive,” or “Unevaluable.” Cases receiving a “Persuasive” or “Supportive” rating are sent to external experts (including oncologists, basic scientists, and clinicians) for further discussion and recommendations on whether NCI-initiated research is warranted for the specific intervention. BCS investigators will use the experts’ opinions to evaluate the utility and estimate the cost of conducting a research study examining the alternative treatment. A recommendation is presented to the Director of the Division of Cancer Treatment and Diagnosis, who makes the final decision regarding subsequent research of the alternative cancer therapy. Practitioners may try to bring attention to their interesting cases on their own; however, the obvious benefit of submitting to the protocol is that it provides another level of oversight to the case histories — it helps validate the information. As a result, Dr. Zia says, “You have the strength of The NCI Best

Case Series Protocol validation standing by you.”

Due to the nature of the NCI BCS program — that doctors have used unconventional treatments, not specifically indicated for cancer — some physicians may be wary about submitting their cases for review. And this wariness may explain why many submitted cases are from outside of the U.S. where alternative medical treatments are more accepted. Dr. Zia notes that the BCS investigators make it clear to submitting doctors that the BCS Program is not out to report them. Rather, states Dr. Zia, “We are researchers interested in seeing those cases and in moving forward” with the science.

“The NCI BCS program continues to provide cancer CAM practitioners a very distinctive opportunity to have their treatment modalities reviewed objectively,” Dr. Zia notes. “Of course, a decision for NCI to pursue follow-up research is the ultimate desire of all submitters; however, other positive outcomes may include having OCCAM publish the case series review in a peer-reviewed journal. This would bring scientific attention to the therapy represented in the case series and may result in research collaborations.”

If you have any questions about the NCI BCS Program or are interested in submitting case reports for review, please visit [http://www.cancer.gov/cam/bestcase\\_intro.html](http://www.cancer.gov/cam/bestcase_intro.html) or contact Dr. Oluwadamilola Olaku (301-435-7980; [olakuo@mail.nih.gov](mailto:olakuo@mail.nih.gov)) for more information. 📧



## A Conversation with:

Sanya A. Springfield, Ph.D.  
Director, Center to Reduce Cancer Health Disparities (CRCHD)

### Would you give an overview of CRCHD and your role as Director?

Established in March 2001, the CRCHD (<http://crchd.cancer.gov>) is central to NCI's efforts to reduce the unequal burden of cancer in underserved populations. These populations include racial and ethnic minorities, the socioeconomically disadvantaged, and the medically underserved from communities across the country. As the Director of CRCHD, I oversee CRCHD's mission by coordinating and strengthening the work of the Center. This work involves collaborating with other NCI divisions and NIH Institutes and Centers to fund research and training initiatives that focus on identifying, understanding, preventing, diagnosing, and treating cancer in our target disparities communities.

Specifically, CRCHD supports grants to fund investigators and institutions that work with our target populations, as well as offering funding to increase the number of competitive researchers in cancer and cancer health disparities research, with particular focus on training researchers from under-represented backgrounds. In addition, CRCHD fosters the development of state-of-the-art regional networks and centers dedicated to cancer health disparities research and care through geographic program management.

### Do you have any current or upcoming CAM projects within your office?

A number of the current projects that CRCHD supports provide funding for CAM-related research. In one recent study, investigators from New Mexico State University at Las Cruces

and the Fred Hutchinson Cancer Research Center—part of CRCHD's Comprehensive Partnership to Reduce Cancer Health Disparities (CPRCHD) program—isolated a new compound from *Datura innoxia*, also known as thorn apple (<http://plants.usda.gov/java/profile?symbol=DAIN2>), a native plant of the Southwest, which has long been used by Native Americans as a topical anesthetic and to treat asthma. Initial in vitro testing of this compound suggests that it works by inhibiting the division of breast cancer cell lines. Further testing in other cancer cells is also being conducted.

In addition, many of our community-outreach programs work to decrease the time between cancer diagnosis and the receipt of quality cancer care for underserved cancer patients, helping them navigate the logistics of modern biomedical treatment. At Boston University, Drs. Karen Freund and Tracy Battaglia have been developing a cadre of patient navigators who can work with members of local minority and immigrant communities. In order to be effective in this role, these navigators—called *promotoras* within Latino communities—work within the cultural environment of their patients and remain aware of the local treatments common within a particular population and how such treatments can interact with and/or complement the biomedical care the patients receive in the hospital. The navigators work within the CAM universe, both acknowledging and incorporating CAMs in their patients' treatment plans, in order to improve their patients' care.

### How do you feel CAM fits in with your mission to reduce the unequal burden of cancer in our society?

CAM is part of the culture of many of the underserved populations with whom we work, including Hispanics, Pacific Islanders, Native Americans, Alaska Natives, Asian Americans, and recently

immigrated Africans. The potential for CAM to promote healing and soothe suffering in cancer patients from these populations is strong and since they are locally acceptable and effective treatments for members of our target communities, CRCHD has a strong interest in supporting CAM research.

Indeed, CRCHD promotes partnerships and programs that draw upon the cultural roots of the populations with whom we work—including using traditional medicine in combination with conventional treatments. Documenting, explaining, promoting, and promulgating such natural, community-based preventions are part of the mission of CRCHD.

### Can you speak a bit about the research of traditional practices that is supported by the Center?

Several of our grantees integrate traditional treatments with modern medicine. Within our Community Networks Programs (<http://crchd.cancer.gov/cnp/overview.html>), Dr. Jeffrey Henderson—a Lakota, enrolled in the Cheyenne River Sioux Tribe—is working through the Black Hills Center for American Indian Health in Rapid City, South Dakota to increase cancer education and training within the Lakota Sioux. As part of the Regional Native American Community Network Program, Dr. Henderson has long been interested in the role of traditional medicines for healing and prevention within his native tribe—most particularly the Lakota's holistic view of health. Some of his current research involves studying lifestyle and behavioral risk factors associated with cancer—particularly lung cancer—among American Indians and Alaska Natives as well as investigating Lakota Sioux attitudes toward biomedical research. Both of these research programs examine how Native Americans integrate

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modern and traditional practices and medicines, both successfully and unsuccessfully, and use those findings to decrease cancer susceptibility.

Ultimately, the work of the Center is interconnected: it moves from the bench to the community and from the community back to the bench. This interconnection is seen in the Center's

fundamental mission to foster research into mitigating health disparities in underserved communities and in training the next generation of competitive cancer researchers from diverse backgrounds. Research conducted by and with diverse scientists and community members can effectively appeal to and mobilize a community's local knowledge and practices—including those that are

CAM-related—towards achieving better health. Acknowledging and supporting these local CAM practices is an important component to substantively and sustainably reducing disparities—and it is in recognizing this importance that the visions of OCCAM and CRCHD most clearly align. 🌿

## News from the Field

### What's the Deal When We Heal? Exploring the Science of Healing

What does it mean when a patient says they are healed? Ask five different people what it means to be healed and you will receive five different responses. Currently, there is no quantitative method available to assess healing. But a new study\* led by Dr. Ann Berger, Chief of the Pain and Palliative Care Service (PPCS) at the Clinical Center, is setting out to change that.

At an event sponsored by the End of Life Palliative Care Special Interest Group (EOL PC SIG) in January, preliminary findings were presented by Dr. Perry Skeath, a PPCS Research Fellow supported by an Intramural Research Training Award (IRTA), from a qualitative study designed to examine healing in cancer patients and survivors and also to help document the results of CAM interventions.

This pilot study is the first step in a larger protocol that will systematically evaluate positive subjective changes in patients. These self-reported changes can be categorized as symptom changes (such as decreased pain or nausea), state changes (such as more happiness or lowered anxiety), or skill changes. Skill changes include the ability to sustain positive subjective experience along with negative subjective experience in the context of negative circumstances; to conserve and efficiently use limited subjective resources (including limited energy and limited coping ability); to make decisions that continue to be reliably satisfying whether healthy, sick,



or dying; and to satisfactorily redesign life during or after cancer.

The participants, who were either cancer patients undergoing treatment or cancer survivors, had participated in a week-long retreat at Smith Farm Center for Healing and the Arts. Smith Farm Center, located in Washington, DC, is a nonprofit organization that offers wellness programs for people with cancer and other illnesses. During the retreat, the participants were exposed to various CAM modalities (including yoga, art therapy, and massage) and were encouraged to incorporate the complementary techniques that seemed most helpful into their routine during and after cancer treatment. To be included in the study, participants must have undergone healing experiences, which were defined as positive life-transforming experiences from their illness. These meaningful experiences were self-defined by the participants. The results of this first study suggest it is skill changes that most often lead to the “life-transforming” personal changes reported by these subjects. When patients take skills that increased substantially during cancer and apply them to the whole of their lives, the result can be “life-

transforming.” During his presentation, Dr. Skeath played audio clips that were recorded during participant interviews. These powerful recordings featured the patients talking about ways they dealt with cancer and how it had also impacted the course of their lives. In particular, a few of the patients discussed how difficult it was to get back to the “real-world” and their everyday lives — new ways of living learned by patients during cancer weren't always compatible with their old ways of living prior to being diagnosed with cancer.

Dr. Skeath commented that one of the surprises emerging from the interviews was “the deep conviction they [the study participants] develop for leading lives that are true to their own nature.” As a result of their illness, a number of the participants actively eliminated aspects of their lives that were not genuine — and this sometimes even included ending close friendships or marriages. Dr. Skeath suggests this may have developed in an automatic way and that some CAM techniques may be involved. He posits that “there is strong reason to believe that many mentally-oriented CAM modalities have enhanced ways to access this automatic-processing aspect of the mind in a very easy, yet constructive way—much more than modern Western psychotherapies. We may be beginning to see what the ‘active ingredients’ of these mentally-oriented CAM modalities are.”

No two patients have identical experiences while battling illnesses, so it is challenging to empirically evaluate patient-reported outcomes.

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\* Protocol number: 09-CC-0227

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NIH has worked with centers across the country to develop a computerized test to standardize responses from patients, known as the Patient-Reported Outcomes Measurement Information System, or PROMIS. The Cancer PROMIS Supplement (CAPS) was created to measure patient-reported outcomes relevant for cancer populations and studies suggest this may be a useful tool.

The interviews from the healing study were compared with the CAPS survey

and it turns out that while some aspects of healing are captured in the CAPS survey, others are not. For example, one of the CAPS questions asked subjects if their experience with their illness had made them more patient. One of the healing study participants commented that she wasn't sure how to answer that question — following her experience, she had developed more patience for certain things (e.g., traffic), but became less tolerant of other things (e.g., people complaining).

While the details of healing experiences may differ for each individual, this pilot study indicates that examining some of the mechanisms and concepts underlying these experiences may help patients and their healthcare providers guide treatment and possibly improve outcomes. For the next portion of this study, the researchers plan to interview cardiac patients as well as a more diverse sample of cancer patients – not only patients who have already had one or more strong healing experiences. 🌊

## Mobile Application Makes Tracking your Dietary Supplements a Little Easier

The NIH Office of Dietary Supplements (ODS) has developed a mobile application that will help individuals track and manage their vitamins, herbs, and other supplements. This application also provides scientifically supported facts about dietary supplements and information about ODS.

Features of the application include the ability to create a personal dietary supplement profile that records the names and amounts of supplements you take, an option to email your supplement list to whomever you like—including your healthcare professionals,

and security settings that allow password protection.

More information is available at the ODS website: <http://ods.od.nih.gov/about/mobile/aboutnyds.aspx>. 🌊

## NCI's CAM FY 2009 Annual Report Released

The National Cancer Institute's Office of Cancer Complementary and Alternative Medicine (OCCAM) is pleased to announce the release of the fifth NCI CAM Annual Report. NCI's Annual Report on Complementary and Alternative Medicine: Fiscal Year 2009 provides an overview of NCI-supported CAM research and highlights research studies, projects, and grants that are supported by NCI's extramural and intramural grant funding divisions.

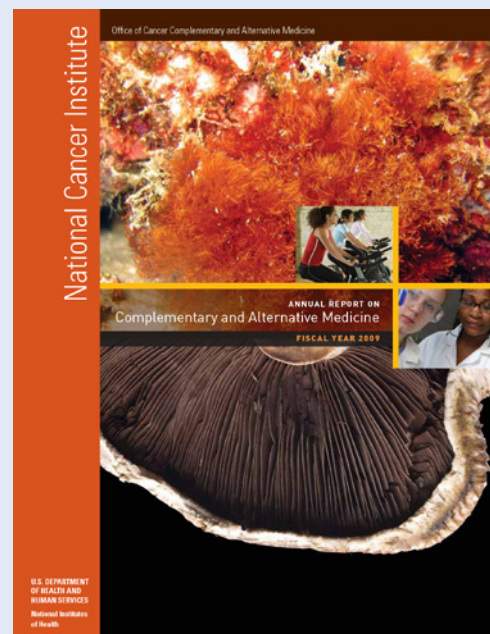
The report includes an in-depth analysis of NCI's CAM research portfolio, summaries of certain CAM research projects, a list of NCI funded peer-reviewed scientific publications, and details on NCI's CAM training, conferences, and communications activities.

Highlights of articles in the report include:

- Large Populations and Rigorous Methods Needed for Vitamin D Research
- Pomegranate Studied as Preventative Agent Against Prostate Cancer
- Exercise and Antidepressants May Counteract Stress-induced Tumor Growth
- Cranial Stimulation Tried for Managing Side Effects of Chemotherapy in Breast Cancer

NCI's Annual Report on Complementary and Alternative Medicine: Fiscal Year 2009 is available for viewing on the OCCAM Website at [http://www.cancer.gov/cam/attachments/nci\\_cam\\_annual\\_report\\_fy09.pdf](http://www.cancer.gov/cam/attachments/nci_cam_annual_report_fy09.pdf).

Past reports are also available for viewing at [http://www.cancer.gov/cam/cam\\_annual\\_report.html](http://www.cancer.gov/cam/cam_annual_report.html). 🌊



## Sign-up for OCCAM's Listserv

Stay up-to-date on the latest cancer CAM news at NCI with OCCAM's listserv, *OCCAM Announcements*. As a listserv subscriber, you will receive a monthly email about upcoming workshops and lectures, new funding opportunities, publications, and other resources. To subscribe, simply visit OCCAM's Web site: [http://www.cancer.gov/cam/news\\_listserv.html](http://www.cancer.gov/cam/news_listserv.html).

### Unlocking the Secrets of Natural Products Used in CAM

Many forms of complementary and alternative medicine (CAM) rely on natural products, such as herbal medicines, botanicals, dietary supplements, and probiotics. The National Cancer Institute (NCI) has a unique interest in researching natural products and their effects on cancer, including identifying natural products that may help prevent cancer and those products which may help to treat it. A joint request for applications (RFA) between NCI, the National Center for Complementary and Alternative Medicine (NCCAM), and the Office of Dietary Supplements (ODS), titled: “Mechanistic Research on CAM Natural Products (R01) (RFA-AT-11-001)” opened on November 1, 2010. The RFA seeks the submission of studies with potential to provide new data on



the biological effects or mechanisms of action of natural products that could further improve the design of clinical studies.

Types of studies that are considered appropriate include (but are not limited to):

- Developing methods to improve purification and characterization of complex natural products.

- Determining active components of natural products.
- Elucidating interactions among components within a single botanical product, between components of mixtures, as well as between natural products and pharmaceuticals.
- Developing tools to measure hypothesized biological effects in clinical trials.

More information on this RFA is available: <http://grants.nih.gov/grants/guide/rfa-files/RFA-AT-11-001.html>.

Researchers are encouraged to contact the NCI program director assigned to this RFA, Dr. Young S. Kim of the Nutrition Science Research Group in the Division of Cancer Prevention, at [yk47s@nih.gov](mailto:yk47s@nih.gov).

### NCI's Collaboration with Fogarty International Center Aims to Address Global Health Needs

The National Cancer Institute and the Fogarty International Center of the National Institutes of Health are collaborating to encourage applications for biomedical research between scientists supported by NIH and investigators in low- and middle- income countries (LMIC). Originally opened on December 10, 2010, this funding opportunity announcement for R03 grants (PAR-11-037) titled: “Limited Competition: Fogarty International Research Collaboration - Basic Biomedical (FIRCA-BB) Research Award (R03),” aims to build partnerships between NIH-funded US researchers

and international investigators to address global health needs. Further objectives of the Fogarty International Research Collaboration Award include helping to build research capabilities and foster sustained and productive research at the selected LMIC institutions. NCI is particularly interested in researching innovative concepts and methods including complementary and alternative medicine, emerging research techniques and technologies, and working with unique populations and environments.

Collaboration with a LMIC is required and this collaborator must be from an institution located in a LMIC as

defined by the World Bank. Several other eligibility criteria that apply to principal investigators at both US and the LMIC institutions are available at the announcement webpage: <http://grants.nih.gov/grants/guide/pa-files/PAR-11-037.html>.

For more information into this unique research opportunity, contact NCI Program Director Dr. Dan Xi, at [xida@mail.nih.gov](mailto:xida@mail.nih.gov). Program directors are knowledgeable in the grant submission process and are available to offer advice. Questions are always welcomed during the application process.

### Funding Available for Research on Diet Composition and Energy Balance (R01)

Due to the increased prevalence of obesity and its association with many chronic diseases, the National Cancer Institute is interested in research focused on dissecting and exploring the complex causes of obesity. An unhealthy diet and imbalanced energy consumption

are known to advance obesity, but how do the foods we eat influence energy balance?

The funding opportunity announcement (FOA) titled “PA-10-152: Diet Composition and Energy Balance (R01),” originally release on March 22,

2010, invites applications for research studies that focus on the role of diet composition in energy balance. This FOA supports both long-term clinical studies evaluating the efficacy of diets differing in micro- or macronutrient composition, absorption, dietary variety, or energy density for weight loss or

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weight maintenance and short-term basic clinical studies investigating the impact of micro- or macronutrient composition on appetite, metabolism, and energy expenditure.

Specific research areas of interest for this FOA include, but are not limited to:

- Studies addressing the impact of diets varying in levels of protein, carbohydrate, fat, phytochemicals, or

ethanol on appetite, food selection and intake, and energy expenditure.

- Studies using complementary and integrative approaches to improve body composition and energy balance.
- Studies examining the role of complex fatty acids (e.g., omega-3 fats EPA and DHA) in microbiota patterns and maintenance of energy balance and glucose metabolism.

- Studies assessing the bioactive attributes of phytonutrients (e.g., green tea) that impact energy balance and weight loss maintenance.

For more information about this program announcement, visit the web page at <http://grants.nih.gov/grants/guide/pa-files/PA-10-152.html>. You may also contact the NCI Program Director assigned to this program announcement contact Dr. John A. Milner at [jm524n@nih.gov](mailto:jm524n@nih.gov).

## Research Resources

### Science Serving People: Your One-Stop Shop for NCI Information

*Newly designed web portal helps researchers and the public sift through NCI information*

The National Cancer Institute (NCI) website (<http://www.cancer.gov>) contains an abundance of cancer-related information, including research news, grant updates, funding information, and general cancer information. Navigating this comprehensive resource just got a little easier, thanks to *Science Serving People*, <http://www.cancer.gov/aboutncil/servingpeople>, a newly updated portal on the NCI website. This portal is designed to make the latest research findings, budgetary information, and advocacy efforts more accessible to the general public by placing the information in one location.

Visitors to the *Science Serving People* site can easily obtain a wealth of local

information including cancer incidence in their state and county. They can also search for nearby clinical trials, including CAM trials. NCI budgetary information is also available — users can see a snapshot of how federal funds are allocated throughout the NCI and how money is distributed for research on specific types of cancers. Through the *Science Serving People* portal, visitors are directed to updates on NCI's advocacy efforts, such as cancer-related hearings, laws, and resolutions being debated in Congress. *Science Serving People* also includes several educational pages. For instance, there is a page devoted to helping the public understand cancer statistics. The website also provides a guide explaining how cancer research

works — from initial lab studies to clinical trials involving patients.

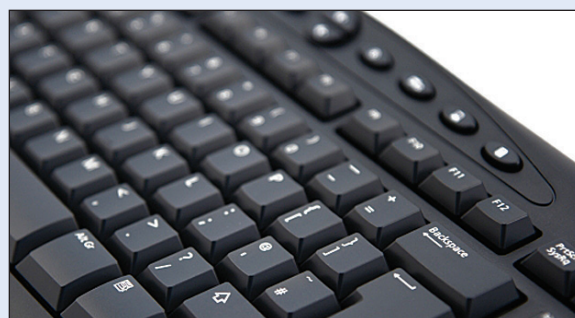
*Science Serving People* can be a useful site for researchers and healthcare providers, as well as for the public. For example, healthcare professionals are able to view tutorials about targeted therapies for breast cancer, lymphoma, and multiple myeloma. The “Cancer Research in Your Community” section of the portal can inform researchers and healthcare providers of NCI partnerships and networks around the country. Overall, the *Science Serving People* website is a comprehensive overview of NCI's many functions and should help researchers and the public learn more about their National Cancer Institute.

### New NIH Extramural Research Office Blog Provides Researchers with Latest Grant Information

The Office of Extramural Research (OER) is known by potential and current grantees as a valuable resource for grant-related information. Everything from submission dates, to funding announcements, to tips and tools for submitting a grant are available at the OER website. While this site is surely bookmarked on researchers' computers around the country and world, it can be difficult to parse out the newest information from what is standard fare. Navigating any website can be a challenge, but when the future of your research is on the line, you want to make

sure you're getting all the latest news and topics in a timely manner.

Enter the new OER blog, *Rock Talk*, eponymously named after OER's Deputy Director for Extramural Research, Dr. Sally Rockey. *Rock Talk*, <http://nexus.od.nih.gov/all/rock-talk/>, aims to educate its audience by “helping you understand the NIH perspective, describing key events and policies, responding to concerns we [OER] are hearing from the extramural community, and allowing



you to comment.” The blog is a mix of information on funding announcements, grant scoring, upcoming events, and

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policy and procedural information for researchers and those looking for grant funding. Comments are open on most posts and lively discussions always follow. *Rock Talk* gives members of NIH and the larger researcher community around the country the ability to sound off on their thoughts about NIH policies. Dr. Rockey even responds to comments occasionally.

Highlights from the blog include:

- Family-Friendly Policies Apply to All Grants
- Correlation Between Overall Impact Scores and Criterion Scores
- Paylines, Percentiles and Success Rates

The blog posts are written in an easy-to-understand format that helps clarify some

complexities of the grant-application process. Overall, the blog is a tremendous resource for researchers and those looking for funding. It gives frank information while allowing the opportunity to comment. Learn more at the *Rock Talk* blog, and by signing up to receive the NIH Extramural Nexus email: <https://list.nih.gov/cgi-bin/wa.exe?SUBED1=extramuralnexus&A=1>.

## Extreme Makeover: Newly Redesigned OCCAM Extramural Research Program Website Provides Better Access to Funding Information

OCCAM has recently reorganized its Extramural Research Program (ERP) website, <http://www.cancer.gov/cam/research.html>. The site is the main avenue within the OCCAM website for learning about funding opportunities, grant application information, and guidance for navigating the NIH grants funding system.

Website visitors can find vast information about NCI's funded

research, exciting research results, and even a list of frequently asked questions. Tools for researchers are also available in an easy-to-read chart that organizes research tools by Institute (e.g. NCI, NCCAM, ODS).

Contact information for OCCAM's Program Officer, Dan Xi, Ph.D. is also available. Dr. Xi oversees several NCI CAM-funded projects; works with potential grantees helping to align their

priorities with the most relevant NCI funding mechanisms for their research; and provides general technical help and support. There are several divisions within NCI, each of which has some CAM research in its portfolio. Dr. Xi can work with the potential grantee to find a funding opportunity that works for them. More information is available on the new ERP website and you can contact OCCAM directly at [ncioccam1-r@mail.nih.gov](mailto:ncioccam1-r@mail.nih.gov).

## Research Highlights

### International US-China Collaboration in CAM Research Leads to New R01 Grant

A new NCI R01 project\* titled "Placebo controlled trial of acupuncture to prevent radiation-induced xerostomia" was awarded in February, 2011 to Lorenzo Cohen, M.D. at the University of Texas M.D. Anderson Cancer Center. Dr. Cohen is currently the principal investigator of a U19\*\* cooperative agreement supporting the ongoing studies of the International Center of Traditional Chinese Medicine for Cancer. The International Center is a partnership between the M.D. Anderson Cancer Center in Houston, Texas and the Fudan University Cancer Hospital in Shanghai, China established to investigate the benefits of Traditional Chinese Medicine on some cancers and cancer side effects.

The new project builds on initial research conducted at the two institutions suggesting that acupuncture can diminish symptoms of xerostomia (dry mouth) in patients who had already developed the condition, and could

also prevent the severity of xerostomia symptoms and improve quality of life in patients undergoing radiotherapy. The proposed multi-center, randomized, placebo-controlled trial will examine the effects of acupuncture at preventing radiation-induced xerostomia in patients undergoing radiotherapy for head and neck cancer (M. D. Anderson) or nasopharyngeal carcinoma (Fudan Cancer Hospital).

OCCAM's Dan Xi, Ph.D.- the program officer of the U19 cooperative agreement- commented that "we are very glad that some of the initial clinical studies performed at the International Center of Traditional Chinese Medicine at Fudan Cancer Hospital have contributed to the scientific basis for this newly awarded R01 grant. The original cooperative agreement has fostered the establishment of an excellent collaborative relationship, a strong experienced clinical research team, and a fruitful clinical research infrastructure for conducting

international collaborative Traditional Chinese Medicine cancer research at both cancer centers."

More information and results from the original U19 and the new R01 can be found at the NIH Reporter database, <http://projectreporter.nih.gov/>, by entering the project numbers located below.

\*Project number: 1R01CA148707-01A1

\*\*Project number: 3U19CA121503-04S1

#### Contact Information

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<http://cancer.gov/cam>



## Literature Review of Studies Investigating Herbal Therapies Used by Cancer Patients

Herbal therapy may be among the most commonly used types of complementary and alternative medicine (CAM) by cancer patients, but how much evidence exists to support the use of these treatments? Oluwadamilola Olaku, Case Review and Intramural Science Program (CRISP) Coordinator, at the Office of Cancer Complementary and Alternative Medicine (OCCAM) and Jeffrey D. White, Director of OCCAM, conducted a literature review, published in the *European Journal of Cancer*, to evaluate the herbal therapies that have had published cancer case reports and those that were subsequently investigated in prospective studies.

Forty-three articles describing 71 cases were included in this analysis. Among these articles were 18 case reports showing apparent anti-tumor effects of herbs used by cancer patients and 21 case reports showing adverse effects of herbal treatments. There were also four case reports in which patients used herbs to relieve disease symptoms. A search for prospective research studies examining these therapies revealed that while some herbs (for example, mistletoe and noni) have been the subject of clinical studies, the majority of herbal therapies have not been additionally investigated following publication of positive case reports.

The authors note there are challenges associated with studying herbal treatments, such as identifying the specific component of a multi-component herbal therapy linked to an effect and difficulties in creating herbal placebos. However, Olaku and White conclude that, despite these hurdles, researchers should consider “prospective research when credible evidence is available suggesting potential benefit to cancer patients from herbal or other unconventional approaches.”

The article abstract can be viewed via PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/21185719>.

## A Natural Catalogue: Herbal Library Created to House Traditional Chinese Medicine Botanical Extracts

In the United States, 38% of adults in 2007 reported using some form of complementary and alternative medicine (CAM) to treat illnesses or prevent the onset of disease, according to national survey data.\* Nearly 18% of adults surveyed had used natural products, making this the most popular category of CAM therapy. Although using herbal and natural medicines has increased in popularity within the US adult population, the scientific community has been hesitant to encourage widespread use of herbal supplements to treat and prevent illnesses. Clinical trials researching the effectiveness of herbal medications have been criticized for their lack of reproducibility and poor quality assurance of the products used. For example, herbal supplements may not be identical in each clinical trial — they may be contaminated or may be produced by different methods, which might affect the way the supplement reacts in the body.

Research conducted in conjunction with an NCI U19 Cooperative Agreement\*\* between investigators from Harvard Medical School, Beijing University of Chinese Medicine, and Hong Kong Baptist University has resulted in the creation of a prototype library of 202 plants and fungi commonly used in

Traditional Chinese Medicine (TCM) herbal prescriptions. According to the research published in the January 2011 issue of the journal *Fitoterapia*,\*\*\* Principal Investigator Dr. Eisenberg and his research team noted that each plant gathered for inclusion in the library underwent rigorous screening criteria to be eligible for submission. With the oversight of TCM botanical experts, each species was collected using Chinese traditional techniques from 2-3 different locations that were precisely documented using GPS. Once they were gathered, the plants were tested for pesticides and heavy metals to ensure that the specimens were in the purest form possible. The samples with the least amount of contaminants underwent additional processing and analysis in the lab to further ensure purity, to identify individual components present in the plants, and to prepare them for use in research studies.

The library, which is housed in Harvard University, aims to establish a future model for systematically evaluating botanicals traditionally used for the treatment and prevention of cancer. This will advance, on a global level, the research that analyzes herbal therapies and their potential for treating and preventing a variety of illnesses. More



information on this research can be found by referencing the journal article available at PubMed, <http://www.ncbi.nlm.nih.gov/pubmed/21108995>.

\*[http://nccam.nih.gov/news/camstats/2007/camsurvey\\_fs1.htm](http://nccam.nih.gov/news/camstats/2007/camsurvey_fs1.htm)

\*\* Project number: 5U19CA128534-04

\*\*\*Reference: Eisenberg DM, Harris ESJ, Littlefield BA, et al., Developing a library of authenticated Traditional Chinese Medicinal (TCM) plants for systematic biological evaluation – Rationale, methods and preliminary results from a Sino-American collaboration. *Fitoterapia*. 2011; 82(1):17-33.

## Cancer Survivors More Likely to Use CAM Compared with Non-Cancer Survivors

There are nearly twelve million cancer survivors in the US and the daily challenges they face with health care and self-care will continue to be a pressing concern for the health care system. A recent study published in the *Journal of Cancer Survivorship* by NIH-supported researcher Jun James Mao, Ph.D. and his colleagues highlights some of the unique differences in the use of complementary and alternative medicine (CAM) between cancer survivors and people who have never had cancer.

Dr. Mao's research is supported by a K23 Career Development Award\* from the National Center for Complementary and Alternative Medicine (NCCAM). In his publication titled "Complementary and alternative medicine use among cancer survivors: a population-based study,"

Dr. Mao and his research team analyzed data from the 2007 National Health Interview Survey (NHIS), conducted by the Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics (NCHS), to learn more about how cancer survivors are using CAM, reasons and motivations for their use, and their communication of CAM use with their health care providers. The study found that cancer survivors were significantly more likely to have ever used CAM in their lifetime compared to non-cancer controls (65% vs. 52.5%). Cancer survivors stated that reasons for CAM use included wellness or general disease prevention, to increase energy, to enhance immune function, treatment of pain-related symptoms, or to help deal with psychological stress

or insomnia. Further discussion of the data brought unique insight into reasons why patients may or may not choose to disclose their CAM use to providers, such as fear of a negative response and physicians not being perceived as helpful or supportive.

Studies of this kind provide a closer look at CAM use in the general population and give researchers, clinicians, and CAM practitioners more information about how CAM is being used in the daily lives of survivors.

For more information on this study, the article can be viewed online at <http://www.ncbi.nlm.nih.gov/pubmed/20924711>.

\* Project number: 5K23AT004112-04

## CAM Information

### Walk This Way: Clinical Center Labyrinth Provides Opportunity for Meditation and Reflection

Meditation labyrinths, also known as prayer labyrinths, have a long history, dating back thousands of years. An individual follows a winding path, leading to the center, and back out again, while meditating, praying, or reflecting. A labyrinth is not the same thing as a maze: There is only one path to follow — to the center and back again — so it is impossible to get lost. Labyrinths are designed to be calming and comforting. One of the most famous labyrinths in the world is at the Chartres cathedral, located outside of Paris. However, NIH patients and visitors do not need to travel all the way to France to experience a labyrinth — there is one located right on the NIH campus.

The Labyrinth, overseen by the Pain and Palliative Care Consult Service (PPCCS), is located in One South East at the Hatfield Clinical Research Center. This 30-foot canvas labyrinth is available for patients, staff, and visitors on the first and third Tuesdays of every



*The thirty foot labyrinth is available for use on the first and third Tuesday of every month at the NIH Clinical Center.*

month from 9:00am until 3:00pm. The Labyrinth is staffed by volunteers and PPCCS employees, who provide guidance for visitors and answer questions. In addition to the large floor labyrinth, there are tabletop labyrinths available. These smaller labyrinths, in which a finger is traced along the path, are for visitors who have difficulty walking.

There are three main phases to walking the labyrinth. The first is "release," as the journey towards the center begins.

Once an individual reaches the center (the "receiving" phase), they can walk back towards the start of the path, simply exit off to the side, or remain in the center for as long as they would like. While in the center, visitors to the NIH Labyrinth have been observed engaging in various behaviors such as Tai Chi movements, praying, and meditating. The final phase is "renewal," when the visitor reflects on their experience.

Labyrinths come in an array of shapes and patterns, but the one at the Clinical Center is an 11-circuit design, similar to the labyrinth in Chartes Cathedral. It consists of four quadrants and a rosette in the center made up of six petals.

Spiritual healing is a major category of CAM that focuses on deep, often religious beliefs and feelings, including a person's sense of peace, purpose, connection to others, and beliefs

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about the meaning of life. According to analysis of the 2007 National Health Interview Survey special subset on complementary and alternative medicine use, conducted by the National Center for Complementary and Alternative Medicine (NCCAM) and the National Center for Health

Statistics, deep breathing exercises and meditation use has increased significantly (13% and 9%, respectively) since 2002. The ability to provide NIH clinical center patients, staff, and visitors an avenue to practice meditation is a welcome addition to the PPCCS mission. Every person who

walks the labyrinth will have a unique experience and the labyrinth represents different things to different people. For example, an NIH visitor may view it as a metaphor for life's journey while a cancer patient may view it as providing a welcome break from having to think about their illness. 🌊

## Spotlight on Cancer and CAM in the *NCCAM Clinical Digest*

The National Center for Complementary and Alternative Medicine's (NCCAM) recently launched publication, the *NCCAM Clinical Digest*, dedicated their October 2010 issue to cancer and complementary and alternative medicine (CAM). The issue highlighted studies that examined different CAM therapies

for cancer prevention, treatment, and side effect management. Research summaries are featured along with links to the original studies. Some of these topics include the anti-cancer effects of white tea extract and ginseng; using massage therapy to affect mood and reduce pain; and investigating claims that

ginkgo biloba can reduce cancer risk. The issue also provided material and resources for cancer patients interested in CAM.

To read the *NCCAM Clinical Digest* Cancer and CAM issue, visit <http://nccam.nih.gov/health/providers/digest/cancer.htm>. 🌊

## And the Awards Go To... PDQ Editorial Boards Receive NIH Merit Awards



*Several members of the PDQ CAM Editorial Board accept the NIH Merit Award. From left to right are Robin Baldwin, Dr. John Beutler, Dr. Gordon Cragg, Dr. Donald Abrams, OCCAM Director Dr. Jeffrey D. White, and NCI Director Dr. Harold Varmus.*

At the 2010 NCI Director's Award Ceremony, an annual event that recognizes outstanding contributions by National Cancer Institute (NCI) employees, all of the NCI Physician Data Query (PDQ) Editorial Boards received NIH Merit Awards. The PDQ Editorial Boards were recognized for the award due to their "dedication and exceptional service to NCI in developing and maintaining evidence-based PDQ cancer information summaries for health professionals and the public."

Donald Abrams, who is a member of the PDQ Complementary and Alternative Medicine (CAM) Editorial Board "was delighted to see that PDQ CAM was

receiving this recognition!" He continues, "The award is actually right here on my desk, reminding me how important it is for the PDQ CAM Board to provide health professionals and the public with the most up-to-date information available on cancer complementary therapies. So many of our patients are integrating other modalities with their conventional cancer care- it is great that the NCI provides this important data!"

Robin Baldwin, Manager of the PDQ Supportive and Palliative Care and CAM Editorial Boards, notes that the award "is a meaningful recognition for the hard work put in by all the PDQ Editorial Board members."

According to the NIH Office of Human Resources Workforce Relations Division (OHR/WRD), the NIH Merit Award is "awarded by Institute and Center Directors and NIH Deputy and Associate Directors to recognize individuals or groups whose superior service and achievement warrant special appreciation."

An NIH employee can nominate an individual or group for the Merit Award by logging onto the OHR website and going to the NIH Employee Awards page (<http://intrabr.od.nih.gov/wits/index.htm>). As part of the application, the nominator provides an explanation of why they are nominating a specific individual or group. The justification should describe the nominee's contributions and the significance of their actions. In addition, the nominator should include a citation — this statement (for example, "In recognition of...") will be engraved on the plaque should the nominee receive the Merit Award.

The Awards Ceremony, which was hosted by Dr. Harold Varmus, Director of NCI, was upbeat and had a number of humorous moments. Abrams commented, "Dr. Varmus did a great job with 'flow' and his sense of humor was even better than I remember from having worked in his lab at UCSF in 1981." 🌊

## Meetings


### OCCAM Director Addresses Pancreatic Cancer Symposium

The Pancreatic Cancer Action Network is a patient-based advocacy and research funding organization. On March 19, 2011, the organization held the Pancreatic Cancer Symposium in Washington, DC, which highlighted advances in disease treatments, symptoms and side effect management, and clinical trials. Attendees included patients, caregivers, researchers, and health care professionals. OCCAM Director, Dr. Jeffrey D. White was invited to present a session on complementary and alternative medicine. Dr. White spoke to the diverse crowd about complementary and alternative approaches to the treatment of patients with pancreatic cancer and

the NCI-funded research supporting these endeavors.

In addition to Dr. White's talk, breakout sessions during the conference allowed attendees to hear in-depth presentations on several topic areas including FDA-approved treatments and clinical trials, information on side effect management through nutrition, and a caregiver support session.

Dr. White's talk titled "Complementary and Alternative Medicine (CAM) and Pancreatic Cancer" presented an overview of the many types of CAM treatments and modalities available, discussed the status of NCI-funded cancer CAM research, highlighted CAM research results, and informed the

audience about clinical trials they may enroll in for pancreatic cancer and CAM. Dr. White noted that the conference session "was very well attended and in the question and answer period there were many good questions about the availability of objective information about several CAM approaches including astragalus and various types of mushrooms. It is clear to me that our office needs to participate as much as possible in meetings like this to learn more about the specific information needs of the people that are making decisions regarding the use of these approaches. I hope that our office will be able to explore this issue more thoroughly with the Pancreatic Cancer Action Network and others." 

## Featured Scientific Meetings

Date	Meeting	Location	OCCAM Staff Attending
March 19, 2011	Pancreatic Cancer Symposium	Washington, DC	Dr. Jeffrey D. White
June 24, 2011	International Symposium on Malignant Mesothelioma	Washington, DC	Dr. Jeffrey D. White

For inquiries on cancer and CAM, please contact  
1-800-4-CANCER (1-800-422-6237).



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