PALLIATIVE CARE RESEARCH COOPERATIVE

Enrolling Cognitively Impaired Patients

The concept of enrolling cognitively imparied patients can be a bit daunting and requires a little more effort on the part of the clinical team. However, this patient population also deserves the opportunity to participate in clinical research. We've gathered a few ideas that you might consider at your institution as you are reviewing potential patients to enroll in the PCRC (and other) studies. We welcome your suggestions and input as we explore this topic over the coming months.

At Four Seasons they have recently begun enrolling cognitively impaired patients. Some strategies they are implementing with this unique patient population are to meet with the Directors of Nursing at specific nursing homes to share with them the details of the study and to consider the patients. Dr. Bull is contacting attending physicians in this setting as well. They are also reviewing their hospice and palliative care database and working with all providers. They are contacting Health Care Power of Attorney's (HCPOA) after the clinicians make first contact and gain interest. The whole team has had good success with these strategies, saying that it takes a little extra effort to get everyone on board but it's worth the effort since there are definitely cognitively impaired patients who can participate in studies.

Marlene McKenzie, the Colorado CRC, has enrolled a number of cognitively impaired research participants. With this protocol change, she has had to re-educate collaborating hospices and hospital referral sources to not exclude cognitively impaired persons from their referral list. Rather, she has explained that the study now includes this population if we get consent from a legally authorized representative.

Although experience is limited and this is a new patient group to recruit, the opportunity is there, but with a little extra effort. Please send in your thoughts and ideas as you start working with this patient population.

Any topics or newsletter contributions are welcome!
Please send them to: Laura Roe at laura.roe@dm.duke.edu

The PCRC is excited to welcome 4 new member sites!

(Read more about each site on the next 3 pages)

Case Western University and Hospice of Western Reserve

Dr. Maryjo Prince-Paul- Site PI

Dr. Maryjo Prince-Paul is an assistant professor at Case Western Reserve University Frances Payne Bolton School of Nursing. She is also a board certified palliative care advanced practice nurse and research associate at Hospice of the Western Reserve. Maryjo will serve as the site PI there and is excited to join forces with such an amazing group of people. As a Fellow of Hospice and Palliative Care Nursing , she has worked with patients with life-limiting illnesses and their families for over twenty years. She has chaired national forums and has served as the co-chair and scientific co-chair of the Annual Assembly of the American Academy of Hospice and Palliative Medicine and the Hospice and Palliative Nurses Association for the last four years, respectively. She holds a joint faculty appointment in the Frances Payne Bolton School of Nursing and the Research Institute of Hospice of the Western Reserve and has an active research program investigating the influence of relational communication and spirituality on life completion in veterans enrolled in home hospice care. In her spare time, she loves taking her daughter (fastpitch softball pitcher) and son (lacrosse and basketball player) all over the country and watching them play! She is still waiting for Dr. Kutner to take her skiing in Colorado!!

Christine Morehead – CRC

The Hospice Institute of Hospice of the Western Reserve and I are thrilled to be part of the PCRC team! For the past year and a half, I have been a member of the Hospice Institute's research team and have been assisting with research development. In my role of CRC, I have had the opportunity to increase my knowledge in both the clinical and behavioral research world. During my undergraduate education, I volunteered as a research assistant and learned both the value of research and the power of an inquisitive mind. At present, I am enrolled in a graduate program for Clinical Mental Health Counseling (I don't think attending college ever ends) and look forward to utilizing this knowledge to have a more in-depth understanding of the needs of our patients. I hope to learn and share recruiting and community outreach ideas with the whole PCRC team!!

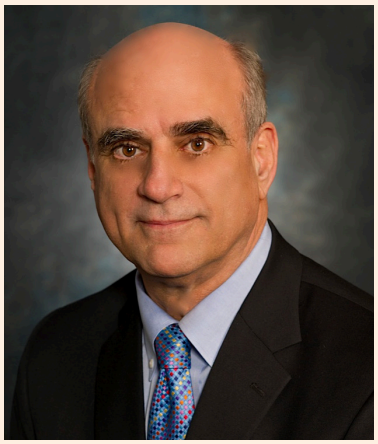
Dr. Janice Scheufler - PharmD

Dr. Janice Scheufler actively participates with the interdisciplinary team in analyses and recommendations of patient-centered, hospice/palliative care pharmaceutical plans of care. In addition to consultation in pain and symptom management, Dr. Scheufler performs drug regimen reviews, pharmacoeconomic studies, quality improvement studies, drug utilization studies, policy/procedure development, and assists in research initiatives. Janice is the lead preceptor for the American Society of Consultant Pharmacist's (ASCP) Pain Management Traineeship. She speaks at the local, state, and national level on a variety of pharmaceutical and hospice/palliative care topics. Prior to joining Hospice of the Western Reserve in 2000, Dr. Scheufler worked in various areas of pharmaceutical practice including hospital, long-term care, and infusion/homecare.

Dr. Charles Wellman - Med Director

Dr. Charles Wellman is a board-certified internist and a fellow in the American Academy of Hospice and Palliative Medicine, received his medical degree from Loyola Stritch School of Medicine in Maywood, Illinois. He completed a residency program in internal medicine at the University of Iowa. In his present position as the Chief Medical Officer of Hospice of the Western Reserve, he is responsible for overseeing the medical care of patients enrolled in their hospice and palliative care programs. He is also a member of The Hospice Institute's research team functioning as principal investigator on multiple clinical research studies. He is also chairperson of his hospice's Ethics Committee and Palliative Care Task Force and has been a member of the ethics committee of NHPCO. He has over 27 years of experience in hospice medicine. He has published articles on pain control and lectures both locally and nationally on end-of-life care.

Capital Caring joins the PCRC!



Capital Caring, one of the premier hospice and palliative care providers in the US, has joined the PCRC. Capital cares for over 1150 hospice patients per day and over 2500 non-hospice palliative care patients annually. Capital operates the Center for Outcomes Research and Education (CORE). The research part of CORE has four main areas of focus 1) clinical trials 2) health services research 3) education outcome research, & 4) data analysis.

Staff Highlights – Research at Capital is a team effort led by Drs. Cameron Muir and Stephen Connor (pictured right) with guidance from CEO Malene Davis and Strategic Policy Consultant Dr. Perry Fine. Cameron is Capital's EVP for Quality and Access and Chief Medical Officer. He is former Chair of the AAHPM and Project on Death in America Fellow. Stephen is consultant director of research for Capital and is well known in the field as former VP for Research and International Development at NHPCO from 1998 – 2008. He splits his time between Capital and his work on international palliative care development as Senior Fellow to the Worldwide Palliative Care Alliance (WPCA) and palliative care consultant to the Soros Open Society Foundations' International Palliative Care Initiative. He is widely published and is the author of Hospice: Practice, Pitfalls, and Promise (1998), Hospice and Palliative Care: The essential guide (2009) and the forthcoming Global Atlas of Palliative Care at the End-of-Life (2012) a WPCA/WHO publication.

Welcome Kaiser Permanente!

Douglas A. Conner – Site PI I received my PhD in animal behavior (animal communication) in 1983 from the University of Colorado Boulder and then began consulting in Biostatisitics at the University. I then received an appointment at the University of Colorado School of Nursing (now the College of Nursing) as a research fellow where I spent 11 years leading research on measuring vocal stress, developing training tapes for new nurses to use to assist mothers to be during second stage labor and a major study in how nurses assess infant pain in the hospital. During a one year period between grant funding. I worked for a workplace disability consulting firm where I led a team that produced a book on workplace disability (The Disability Advisor) for large corporations. In 1997 I came to Kaiser Permanente Colorado as a biostatistician in the region's research department. I served as a biostatistician on several projects in geriatrics and chronic care program evaluations but over the past several years I have developed my own research program in geriatric rehabilitation, palliative care and hospice as well as the ethical challenges unique to these populations. I have been a member of The Denver Hospice's Ethic Committee for several years. I am also involved in Kaiser Permanente's efforts to address some of the potential impacts of the affordable care act on our organization. I have worn a number of different hats over the years but I think I have found the one I am most comfortable with here at Kaiser Permanente. I am very excited that our region is participating in the Statin Discontinuation Trial.

Siteman Cancer Center at Washington University School of Medicine and Barnes Jewish Hospital

Washington University School of Medicine (WUSM) has a rich history of success in research, education and patient care, earning it a reputation as one of the premier medical schools in the United States. Currently, the school has 1,874 full-time faculty members. WUSM received more than $447 million in grants from the National Institutes of Health, making it the fourth largest recipient of NIH dollars among the 123 U.S. medical schools. Barnes-Jewish Hospital (BJH) is a 1,259 bed teaching hospital- the largest in Missouri. The Siteman Cancer Center was designated by the National Cancer Institute as a Comprehensive Cancer Center in 2004, the only such center for a radius of 240 miles. Washington University physicians treat more than 11,600 new cancer patients and follow more than 32,000 annually.

Nina Wagner-Johnston, MD- Site PI

Dr. Wagner-Johnston is an assistant professor of medicine at Washington University School of Medicine. She is board certified in medical oncology and specializes in lymphoma and supportive care. Nina's career began as an oncology staff nurse after graduating with her BSN from Georgetown University. After transitioning to a research nurse position, she became fascinated with the pathology of cancer and decided to enter medical school. She completed her medical school and residency training at the University of Chicago and did a fellowship in medical oncology at Johns Hopkins. Nina's nursing background influenced her decision to focus on supportive care-related research. She is thrilled to become involved with the PCRC and gain mentorship and build relationships with experts in the field.

Anna Roshal, MD-Site PI

Dr. Roshal is an assistant professor of medicine at Washington University School of medicine. She is board certified in medical oncology, and had just taken her Palliative Care board certification exam (results pending). She completed her training at the University of Rochester School of Medicine and Dentistry, including Medical oncology and Hematology fellowship. After spending 4 years in private practice, Dr. Roshal transitioned to clinician-educator career path, and serves as teaching attending on the Inpatient medical oncology service, as well as teaching attending for first year fellows' clinic. As part of her commitment to the field of palliative and supportive care, Anna is in the process of building an outpatient Symptom Control/Palliative care clinic at Siteman Cancer Center. She is very excited to become part of PCRC and help to advance the field of Palliative Care, as well as gain mentorship from experts in the field.

Elizabeth Pennycook, MSW-CRC

Elizabeth Pennycook has worked in the geriatric field for the past seven years. Most recently, she was manager of an outreach program at Washington University School of Medicine. This program was targeted at underserved, community-dwelling older adults living in St Louis City. The program educated older adults about their bone health, osteoporosis, calcium, vitamin D, balance and mobility. The goal of the program was to decrease falls and empower older adults to take control of their bone health. Prior to coming to Washington University, she worked as the social worker and volunteer coordinator for two hospices in the St Louis area. She looks forward to applying her background with older adults and her skills as a social worker to this research study.

Statin Trial enrollment summary (as of November 15, 2012)

Site	Last month's Accrual	Cumulative Accrual	Enrolling in statin trial / cognitively impaired patients
01 - Colorado	9	75	✓ / ✓
02 - Duke	2	38	✓ / ✓
03 - Four Seasons	4	30	✓ / ✓
04 - UNC Chapel Hill	1	28	✓ / ✓
05 - UA Birmingham	5	25	✓ / ✓
06 - Beth Israel	1	2	✓ /no
07 - UW Madison	1	7	✓ / ✓
08 - San Diego Hospice	2	9	✓ / ✓
09 - Northwestern	3	9	✓ / ✓
10 - Mayo Clinic	0	2	✓ / ✓
11 - Mt. Sinai	0	1	✓ / ✓
12 - Kaiser Permanente Colorado	-	-	✓ / ✓
13 - Hospice of Western Reserve and Case Western University	-	-	✓ / ✓
14 - Washington University	1	1	✓ / ✓
15 - Capital Caring	-	-	no/no
Total	**17**	**227**	

CONGRATULATIONS!!!

The PCRC team at Washington University achieved the fastest time from study initiation to first participant enrollment so far!

(Only one day!!)

PCRC TOP: OBTAINING AND DOCUMENTING INFORMED CONSENT

Palliative Care Research Cooperative (PCRC) Team Operating Procedure	
Title: **Obtaining and Documenting Informed Consent**	Page **1** of **3**
Procedure ID: TOP 07	Effective Date: 30 July 2012
	Review Date: 01 August 2013

Palliative Care Research Cooperative (PCRC) Team Operating Procedure: Obtaining and Documenting Informed Consent from Research Participants

I. Background and Purpose

The purpose of this document is to describe the process by which informed consent is obtained from potential study participants, or in the case of potential participants who are cognitively impaired, from their legally authorized representative (LAR). This task involves a discussion between study personnel and the eligible individual about the purpose, procedures, benefits and risks (potential, known, and unknown) of the specific research study for which the individual is eligible, and a review of the informed consent document. The process is designed to enable the potential participant or his/her LAR (for cognitively impaired individuals) to make an informed choice about whether or not he/she would like to participate in this specific research study. If the potential study participant indicates clearly that he/she wishes to enroll, this desire must be documented in accordance with this procedure and all applicable Federal and local regulations and policies.

II. Scope

The process outlined in the document applies to the informed consent process, which is integral to the conduct of any PCRC clinical trial involving human participants.

III. Definitions

1. **Informed Consent:** A process by which a potential study participant voluntarily confirms his or her willingness to enroll in a particular trial, after having been informed of all aspects of the trial that are relevant to the decision to participate. Informed consent is documented by means of a written, signed and dated consent form, unless otherwise specified within the context of an IRB-approved trial protocol. The informed consent document serves as a contract between the study investigators and the study participant, and outlines the participant's rights and responsibilities.
2. **Institutional Review Board (IRB):** An independent body duly constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects (i.e. study participants) involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the participants.
3. **Study Participant:** An individual who consents to participate in a research study/clinical trial, either as a recipient of the intervention under study or as a control participant.
4. **Protected Health Information (PHI):** Any information about health status, health care provision, or health care payment that can be linked back to a specific individual (Ex: Date of birth, initials, address, etc.).
5. **Health Insurance Portability and Accountability Act (HIPAA):** Public Law 104-191, enacted by US Congress in 1996. HIPAA enacted the first national standards for the privacy protection of certain individually identifiable health information known as Protected Health Information (PHI) and its management. The other HIPAA Administrative Simplification Rules provide national standards for electronic health care transactions and code sets, unique health identifiers for employers and health care providers, and the security of electronic PHI.

6. **Legally Authorized Representative:** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(c)). The regulations state that "no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative" (45 CFR 46.116). The issue as to who can be an LAR is determined by the laws of the jurisdiction in which the research is conducted (e.g., local or state law). Some states have statutes, regulations, or common law that specifically address consent by someone other than the subject for participation in research. Most states have no law specifically addressing the issue of consent in the research context. In these states, law that addresses who is authorized to give consent on behalf of another person to specific medical procedures or generally to medical treatment may be relevant if the research involves those medical procedures or medical treatment.

IV. Responsibilities

Any PCRC personnel who will obtain informed consent from study participants, document this information, and/or be involved in the informed consent process in any way will be responsible for the process outlined in this document.

V. Procedure

General Principles:
The process of educating individuals who are potential research participants about the study begins during the initial contact related to the study, and continues for the duration of their participation in the study; ideally, participants also are informed of the study results when analyses are complete.

In the case of recruiting and enrolling cognitively impaired research participants, the same principle applies to his/her LAR. As noted above, each state may have different regulations and definitions as to who may be considered a LAR. The Site PI for each site is responsible for researching and adhering to the regulations and definitions required by state law as well as by that institution's local IRB.

In educating the participant about the study, whether prior to informed consent, during participation, or subsequently, technical and medical terminology should be avoided; concepts should be explained in "lay" language, and materials should be written at a fifth grade reading level or lower whenever possible. The relevant local IRB/Ethics committees must approve any information (including recruitment materials) provided to potential study participants before, during, and after the informed consent process.

The initial informed consent discussion should be planned in advance, scripted, and practiced in a role-play setting. Potential questions that may arise should be anticipated through this exercise, and appropriate responses scripted and practiced. The initial discussion should be timed so as to allow potential participants sufficient time to reflect on the potential benefits, risks and possible discomforts of participation prior to making their decision. Steps in obtaining informed consent are as follows:

1. Potential participants are given general information about the research (e.g., through advertisements, information sheets, letters or discussion with their treating physicians), and if they are interested in learning more about the study, the study staff will contact them.

2. The CRC then meets with the potential participant to discuss the details of the research study using the informed consent document as a guide.
3. This discussion should include all of the required elements of informed consent, e.g., the purpose of the research, the procedures to be followed, the risks and discomforts as well as potential benefits associated with participation (both for the participant him/herself and for future individuals), and alternative procedures or treatments, if any, to the study procedures or treatments.
4. If desired, potential participants may take a copy of the informed consent document home in order to carefully read the document and discuss the research with their family, friends and/or physician and develop questions to ask at their next meeting with the research staff. If the potential participant has given verbal consent to participate in the study but has not signed the consent form and would like to have the opportunity to mail it back to the CRC/site PI, that is acceptable as long as the verbal consent was heard by the CRC and one other witness.
5. Participants must be given the opportunity to ask questions and have them answered by the investigator and, whenever possible, to consult with friends/family and/or their physicians. Once they have read the consent document and their questions are answered, if they agree to participate in the research, they sign and date the informed consent document. A witness (the CRC or other authorized study staff member) also will sign and date the consent document. See point 4 above should there be a situation in which the individual provided verbal consent but did not sign the form in the presence of the CRC. Two people must have heard the verbal consent.
6. The original, signed informed consent document is considered a Source Document. It will be retained and made accessible during any authorized study audit, according to the TOP for Source Documents. Depending upon institutional practice, the informed consent document (copy or original) also may become part of the individual's medical record.
7. The study participant should be given a copy of the signed and dated consent form for his/her records. In the case where a legally authorized representative signs the informed consent for the study participant, the signed and dated copy is given to that individual.
8. The Privacy Rule and HIPAA also are addressed during the informed consent process, and the consent document is written authorization for the use and disclosure of their identifiable information (PHI) for research purposes (or is accompanied by a separate document, per site IRB policy). No study-specific procedures, interventions, or tests (including 'screening tests') may be conducted until informed consent has been obtained and documented.

HISTORY OF CHANGES:
Version A: Original
Version B: July 30, 2012: to include cognitively impaired study participants and language related to LAR.

References: Department of Health and Human Services website: http://answers.hhs.gov/ohrp/questions/7264