



**PALLIATIVE CARE
RESEARCH COOPERATIVE**



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Meet the PCRC team

Greetings, PCRC members and our expanding PCRC community!

And welcome to our first newsletter. You can expect to receive future issues, from this point forward, every two months. The newsletter will be our vehicle for informing you of project updates, communicating about progress, sharing best practices, especially as related to our collaborative studies, and learning from one another's experiences.

As the PCRC's first clinical trial – the "statin discontinuation study" – comes into full swing, our purpose in this first newsletter is simply to introduce ourselves to one another, and to begin to share experiences and success strategies. At this point, early in the trial, these relate to recruitment. We thus hope to set the stage for collaboration of the best sort, that is, cooperative effort in which the combination of our separate strengths, perspectives, knowledge, and unique experiences creates a whole (the PCRC) that is much greater than the sum of its parts.

Please note that, as we go to press with this issue, not all PCRC member sites have been able to provide introductory material. We are all so busy! Stay tuned for introductions from other sites in future newsletters.

Duke University Medical Center

Duke Medicine is a large academic medical center located in central North Carolina; it comprises comprising Duke University Health System, School of Medicine, and School of Nursing as well as numerous research institutes including the Duke Clinical Research Institute, the world's largest academic research organization. Duke's clinical enterprise covers a large portion of our own state as well as drawing patients from neighboring Virginia, South Carolina, and Georgia. Duke University Health System employs over 22,000 individuals; in 2010, it received 1.8 million outpatient visits.

In addition to placing high value on research, Duke Medicine maintains a strong commitment to community-based care and service. Our Health System includes community hospitals (Durham Regional Hospital, Duke Raleigh Hospital), Duke

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University of Colorado at Denver

Those of us on the University of Colorado School of Medicine (UCSOM) team are lucky to live in one of the most beautiful states in the nation. The Anschutz Medical Campus is the only academic medical center in the region, and consists of seven major organizational units: the schools of Medicine, Dentistry, Public Health and Pharmacy, the College of Nursing, the University of Colorado Hospital (UCH) and Children's Hospital Colorado, central services, and administration. The UCSOM has a full-time faculty of approximately 700 and a clinical faculty of 3,700.

Jean Kutner, MD, MSPH, founding Co-Principal Investigator of the PCRC, is a Professor of Medicine in the Divisions of General Internal Medicine, Geriatrics, and Health Care Policy and Research in the Department of Medicine at the UCSOM. She

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University of Wisconsin Carbone Cancer Center



Tip of the week from Wisconsin
 When discussing the study with a physician not familiar with the study or with research, make it clear that “the study” decides if the participant should stop or continue statin therapy; not the (primary) physician. We have lost participants because the primary MD stopped their statin therapy after we spoke with them about the study.

Dr. James Cleary, Co-Investigator, and the Palliative Care Supportive Oncology Working Group (PCSOWG) are coordinating the statin discontinuation study at the University of Wisconsin Carbone Cancer Center (UWCCC).

The PCRC team in Wisconsin includes Dr. Cleary, Dr. Toby Campbell, Renae Quale, RN (Lead Study Coordinator) and Nancy Gidal, RN (Clinical Research Coordinator). Through our affiliation with PCSOWG, we are working with more than 40 physicians throughout UWCCC to enroll study participants. Dr. Cleary and Dr. Campbell are also very involved in the Palliative Care Services at UW Hospital and Clinics, and this affiliation allows us to enroll non-oncology patients into the study.

We officially opened the statin discontinuation study at UWCCC on November 28, 2011 and currently have three participants.

Mount Sinai

Founded in 1852, Mount Sinai Hospital is one of the oldest and largest teaching hospitals in the United States. Located in the heart of New York City (thus representing, in the PCRC, the pinnacle of the urban), Mount Sinai Medical Center encompasses Mount Sinai School of Medicine and Mount Sinai Hospital, a 1,171-bed, tertiary-care teaching facility. Our faculty number more than 3,400, with affiliations in 38 clinical and basic science departments and centers.



R. Sean Morrison, MD, FAAHPM, is Co-Investigator and lead for statin discontinuation study at Mount Sinai. He is Director of the National Palliative Care Research Center, a national organization devoted to increasing the evidence base of palliative care in the United States, and also the Vice-Chair of Research, Professor of Geriatrics and Medicine, and Hermann Merkin Professor of Palliative Medicine in the Brookdale Department of Geriatrics and Palliative Medicine at Mount

Sinai. Dr. Morrison’s research focuses on decision making at the end of life, pain and symptom management in high-risk and medically underserved populations, and quality measures in palliative care. He is an active clinician who cares for both healthy older adults and for persons living with serious and life threatening illness.

Melissa Diamond, MPA, is our Clinical Research Coordinator; she has an extensive background in research and has worked over 10 years with the underserved populations of New York City.

Mount Sinai received IRB approval for the statin discontinuation study on July 7, 2011. Recruitment and screening for the study started in late November 2011 after our annual review was finally approved, but we have yet to enroll their first study participant. It has been a slow process, as we work diligently on exploring different avenues of focus to maximize recruitment. (See text box.)



Sean Morrison



Melissa Diamond

“On the ground” at Mt. Sinai

Principal challenge: Finding individuals who meet eligibility criteria from the current screening pool (Most patients screened are either considered “too healthy” or have dementia.)

Strategies to overcome it:

- working with different Sinai affiliates such as Visiting Docs and Visiting Nurse Hospice services, with the intention of recruiting patients from their rosters
- generating a report that actively lists all patients who are currently on statins for these affiliated sites

We are hoping to share good news regarding recruitment with the PCRC Operations committee very soon, as we are dedicated the PCRC mission.

Duke (Continued from page 1)

HomeCare and Hospice, and Duke Primary Care. Many Duke physicians have active clinical and/or research affiliations with the Durham Veterans' Administration Medical Center, adjacent to Duke University Hospital.

PCRC Co-Principal Investigator Amy Abernethy, MD, is an Associate Professor of Medicine in Duke's School of Medicine, as well as an Associate Professor of Nursing at the School

of Nursing. She is founder and Director of Duke Cancer Care Research Program and Medical Director of Oncology Quality, Outcomes, & Patient-centered Care for Duke Medicine. An active clinician-researcher, she focuses her research on (a) facilitating evidence-based practice in palliative care by adapting or developing innovative clinical trials methodologies, and (b) investigating new interventions to improve symptom control. Dr. Abernethy is also an internationally recognized expert in health services research and patient-centered cancer care, and a national expert in cancer health policy and comparative effectiveness research. In fact, she has become known as one of the main thought leaders working to design an integrated health care/research environment in which IT-enabled systems simultaneously inform clinical care, research, and quality improvement activities. She is a leading voice for developing "rapid learning systems" to advance cancer care in America and globally.

Recruitment for the PCRC statin discontinuation trial began at Duke in July 2011. Currently we have 18 participants enrolled. Our initial recruitment experience helped provide valuable insight to other PCRC sites as they established and modified recruitment strategies to fit their sites' individual needs. (See text box.) Duke patients and staff have been very supportive, and we believe our expansion prospects will be successful as well.

University of Colorado (Continued from page 1)

has over 15 years of experience conducting multi-site studies in, and providing direct patient care for, the hospice/palliative care population. Her primary research focus is improving symptoms and quality of life for this population and their family caregivers.

Rachael Bennett, MA, the Project Director of both the statin discontinuation trial and the Statistical Center and Data

Management (SCDM) is a Research Associate in the School of Medicine and has over 15 years managing complicated, multi-site, research studies. She has worked on three NIH studies, and a myriad of projects for CMS and ASPE (Assistant Secretary for Planning and Evaluation) in the Department of Health and Human Services.

Marlene McKenzie, RN, MN, the Clinical Research Coordinator for the statin discontinuation trial, is a seasoned recruiter with a proven track record for enrolling study participants and over 30 years of nursing and management experience.

To boost enrollment...

At Duke, we have taken several steps to increase our rate of enrollment:

- ❖ recruiting in outpatient clinics and treatment centers, as well as on inpatient units;
- ❖ expanding our recruitment beyond Duke Oncology to other Duke-affiliated sites such as Duke Raleigh Hospital;
- ❖ working with the Duke General Medicine team;
- ❖ introducing the study to the oncoming residents on a monthly basis; and,
- ❖ reaching out to the Duke Clinical Pharmacy team, in hopes that they will become a helpful resource to our PCRC team.

We are exploring the idea of recruiting participants from non-assisted as well as assisted living communities within the area.

The PCRC's SCDM group, led by Diane Fairclough, DrPh, and Patrick (Jud) Blatchford, PhD, has appointments in Colorado Health Outcomes Research, which is housed in the UCSOM. With over 40 years of combined experience, these statisticians are well-equipped to lead the SCDM. To round out the team, we have Monica McNulty, our data analyst and MS Access guru, and Patrick Hosokawa, who runs the randomization website for the statin trial.

We received IRB approval for the statin discontinuation study on June 3, 2011 and enrolled the first study participant on June 7, 2011. To date, we have enrolled 23 study participants, thanks to the hard work, persistence, and tenacity of Marlene McKenzie. As she has said, "this is the hardest project for which I have had to recruit." Take that to heart as you struggle to meet your sample size goals and find yourself running into roadblocks and gatekeepers!

"this is the hardest project for which I have had to recruit"

FOUR SEASONS

Compassion for Life

Four Seasons Compassion for Life is a non-profit, community-based, hospice and palliative care provider organization in mountainous western North Carolina. Four Seasons is an innovator in the field of palliative care in that we offer services integrated across the continuum of settings in which patients are located; we provide care in three hospitals, all 30 area nursing homes, 24 assisted living facilities, our own 19-bed inpatient facility, two clinics, patients' homes, and schools. We are working with a Duke team led by Amy Abernethy to ensure continuity of care,

longitudinally evaluate quality and outcomes, and coordinate across settings through implementation of an IT-enabled data system. We have an active Research Department, and have conducted over 30 investigator-initiated studies and pharmaceutical studies since 2005.

Janet Bull, MD is the site Principal Investigator at Four Seasons for the statin discontinuation study. She is Four Seasons' Medical

Director, leads its Research Department, and serves as the Principal Investigator for all of our studies. She dedicates her research efforts to helping develop best practices that will enable clinicians to improve symptoms and quality of life for individuals with life-limiting illnesses.

We have two ACRP certified Study Coordinators, Lisa Massie and Jennifer Short. With 19 years clinical research experience, Lisa

is our Clinical Research Team Leader. She has been involved with over 150 studies in a variety of therapeutic areas. Jennifer is the primary Study Coordinator for the statin discontinuation study. She has been involved with clinical research for seven years and has conducted a variety of vaccine studies and also has experience working with Internal Medicine programs.

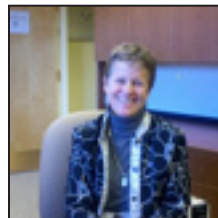
We began enrolling study participants in September 2011. To date, we have screened 14 patients and enrolled 9 participants.

At Four Seasons... 64% success rate! (patients screened/patients enrolled)

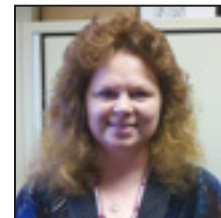
Recruitment at Four Seasons has been most successful in the hospice population.

Recruitment methods:

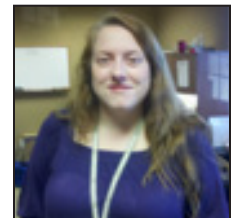
- chart review both in-house and in community offices
- lunch-n-learns
- attending provider meetings
- weekly e-mail reminders to providers and nursing staff



Janet Bull



Lisa Massie



Jennifer Short

The University of North Carolina (UNC) is located just a short trip down "Tobacco Road" from Duke in lovely Chapel Hill, where the skies are always Carolina blue. UNC-Chapel Hill opened its doors as the nation's first public university in 1795 (yes, older even than Mount Sinai!). UNC Hospitals is a public, academic medical center made up of NC Memorial Hospital, NC Neurosciences Hospital, NC Women's Hospital, NC Cancer Hospital, and NC Children's Hospital.



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Investigator; Kathryn Wessell, Project Coordinator; Kelly Onyenwoke, MPH, Clinical Research Coordinator; and Charlotte Rowe, NP, AOCN, ACHPN, Research Nurse. Since receiving IRB approval on October 7th, 2011, we have screened thousands of charts and enrolled six participants.

The research team is currently recruiting from the inpatient Palliative Care consult service, inpatient Oncology, Geriatric, General Medicine, and Hospitalist services, outpatient Oncology and Geriatric clinics, and two hospice organizations. We are also in the process of expanding recruitment into a local long-term care facility.

RECRUITING TIPS

PREPARE

- Believe in the study and its potential benefits to the target population. Have confidence that appropriate, eligible patients are able and willing to participate.
- Know the protocol and consent form
- Practice presenting all study elements in a friendly, conversational manner.

CONNECT

- Dress with respect for patients and families.
- Favor soft colors and comfortable but professional styles, to convey warmth.
- Introduce yourself with a warm entry and hello.
- Maintain good, but not overbearing, eye contact. Smile.
- ❖ **Ask permission and normalize the subject:**
“Can I have a few minutes to tell you about a study we are doing for people like you who are dealing with advanced illness?”
 - ➔ If yes, pull up a chair. Establish by what name they would like to be called.
 - ➔ If not a good time, determine when to come back (if appropriate).

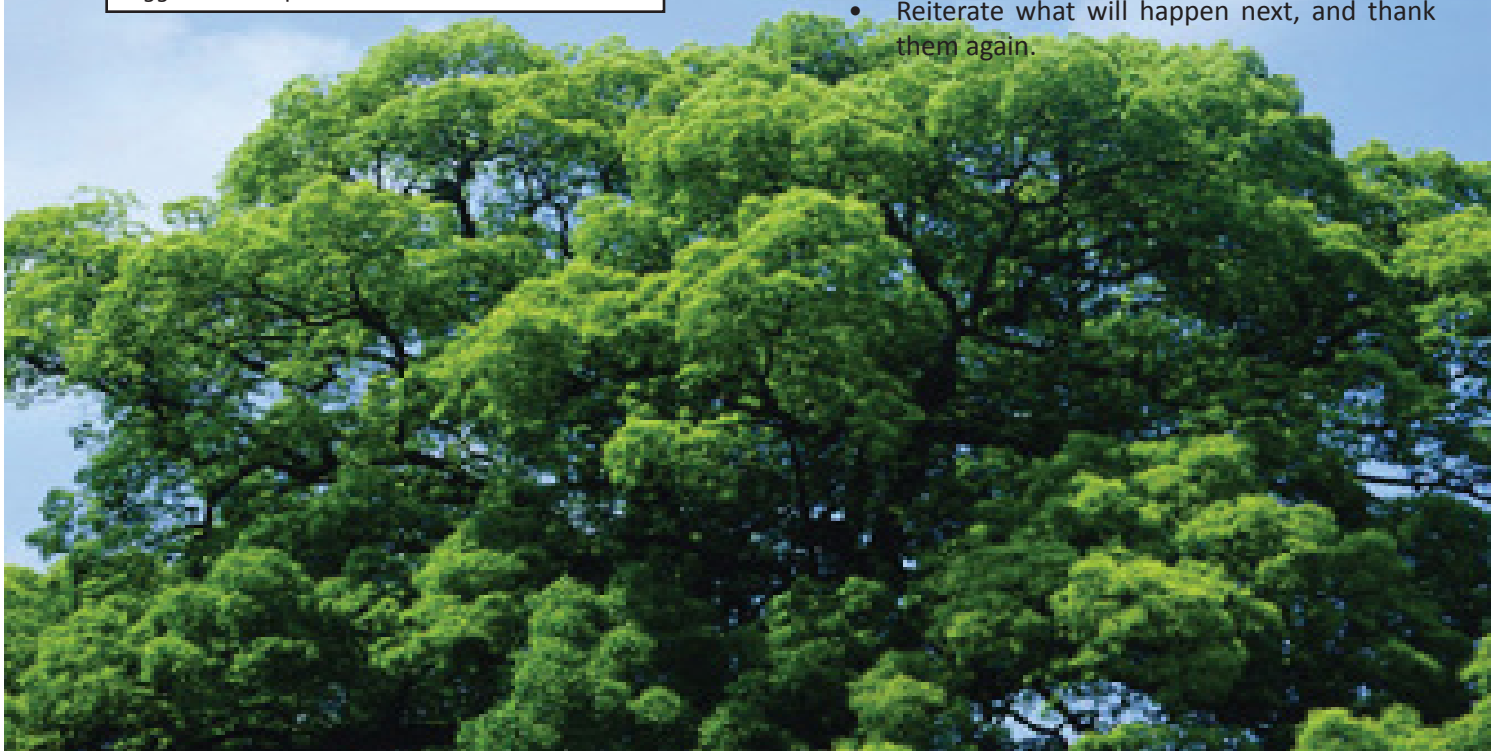
Marlene McKenzie, CRC on the Colorado PCRC team and an experienced recruiter, offered these suggestions to optimize recruitment.

COLLABORATE

- Adopt a stance of collaborating with the patient and family in furthering knowledge.
- Offer the opportunity to participate in a conversational manner. The message is that you are going through the process together.
- Provide copies of materials.
- Keep your voice tone low; speak slowly and loudly enough for seniors to hear.
- Stop periodically to make sure they understand, and to allow them to ask questions.
- Inform patients that you have talked with their physician and he/she has given permission for you to offer this study to them.
- Provide reassurance that participation is voluntary and that they can discontinue participation at any time with no repercussions. Build trust.
- ❖ **Ask:** Would you like to or would you be willing to participate in the project?
 - ➔ If no, thank them for their time and wish them well.
 - ➔ If yes: obtain required signatures

APPRECIATE

- Thank them for their time and if appropriate, helping us learn so that we can help improve care for other people like themselves in the future.
- Reiterate what will happen next, and thank them again.



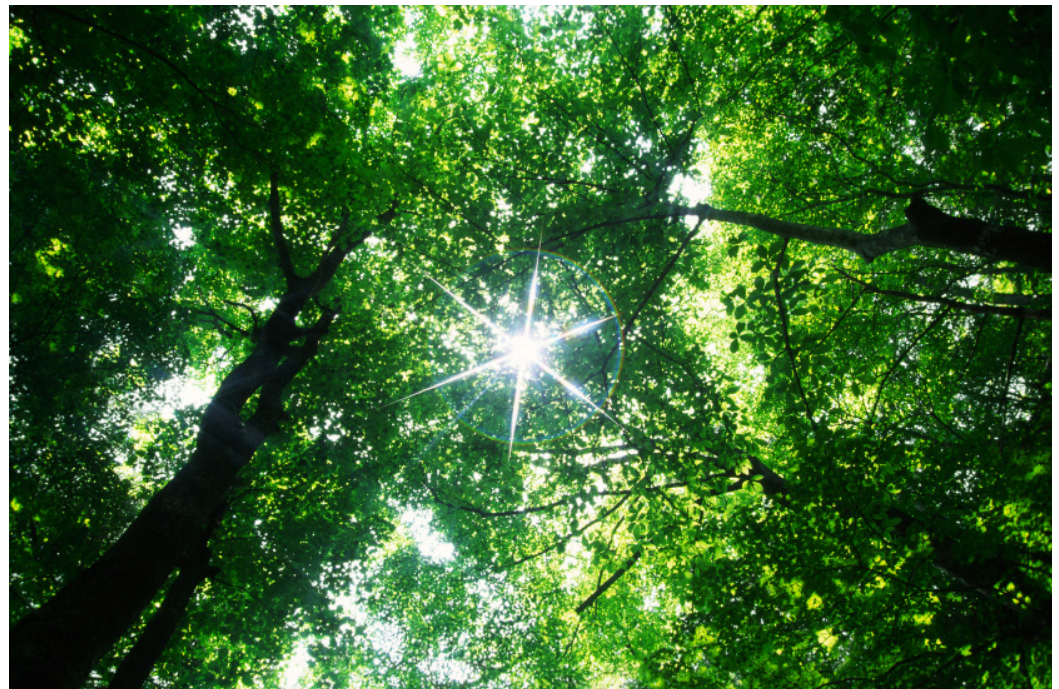
“Field Notes”



Mayo Clinic

“Hello, PCRC Colleagues! At Mayo, recruitment has been impeded by difficulty in hiring a Clinical Research Coordinator. Once we have our personnel in place, we will begin recruiting ASAP from both of our hospitals and our palliative medicine clinic to start. We will likely branch out to our geriatric clinicians as well. We appreciate your support through this process!”

Jeff Sloan, MD, site Principal Investigator



Mission

Develop scientifically-based methods that lead to meaningful evidence for decreasing the suffering of patients with advanced or potentially life limiting illnesses and their care givers, including family members and providers of care.



From the team in Denver, support is available!

We are here for you, and encourage you to continue to participate in the bi-monthly CRC calls and Investigator Office hours to foster a sense of community, learn from each other, and feel the support of those in the cooperative group. We are also available to answer data-related questions at

pcrc.scdm@ucdenver.edu

“Field Notes” - University of Alabama Birmingham

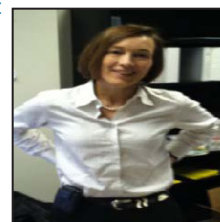
The University of Alabama Birmingham (UAB), led by Christine Ritchie, MD, site Principal Investigator for the statin discontinuation study, and Will Callans, Clinical Research Coordinator, report that...

- IRB approval was obtained on August 31, 2011
- Recruitment began on December 8, 2011

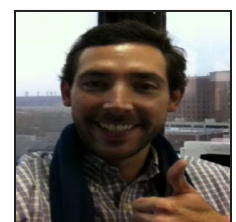
- Three participants have been enrolled and randomized
- Recruitment sites to date include UAB Palliative Care Unit and UAB Inpatient Oncology
- Future recruitment sites include hospice agencies and Outpatient Palliative Care Clinic

Our recruitment strategies:

- Utilize study eligibility cards
- Establish rapport in high volume referral areas
- Adapt to dynamic patient population



Christine Ritchie
Site PI



Will Callans
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Who's Who

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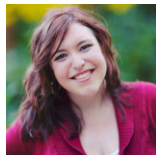
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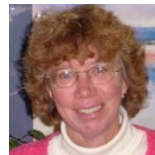
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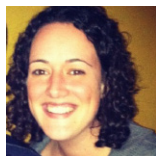
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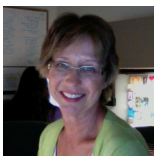
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Data Management/Statistical Trial Specific Issues	Jud Blatchford, PhD
IRB/Regulatory	Jordan Lodato
Membership Committees, Charter	Amy Abernethy, MD or Jean S. Kutner, MD, MSPH
New Research Trial Ideas	Amy Abernethy, MD or Jean S. Kutner, MD, MSPH

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