PALLIATIVE CARE RESEARCH COOPERATIVE

New Member Orientation

Version Date: 19 March 2015

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PALLIATIVE CARE RESEARCH COOPERATIVE

Chapter 1: INTRODUCTION

Welcome to the PCRC Community

We would like to take a moment to welcome you and thank you for joining our community that is committed to improving the lives of people with advanced illness, as well as their loved ones and professionals who care for them.

This presentation is designed to provide this information and serve as a resource for you when questions arise in the future.

Purpose and Goals of Orientation Materials

1. Ensure all new members receive consistent, relevant, timely, and meaningful information upon joining the PCRC.
2. Highlight the benefits of PCRC membership and how participation can and will enhance future research.
3. Identify what the PCRC expects from its members.
4. Provide PCRC history and future vision.
5. Explain how to conduct research within the PCRC.
6. Ensure new members know how to obtain information, and who to contact.

PCRC Vision

Excellent palliative care at the bedside is contingent on best evidence and a scientific underpinning for what we do, so that:

- No patient dies alone, in pain, or without dignity.
- Palliative care responds effectively to suffering at all points in the life/illness trajectory.
- Palliative care enhances *living*.

PCRC Mission

To develop **scientifically-based methods**

that lead to **meaningful evidence**

for **improving quality of life** of **patients**

with advanced and/or potentially life-limiting illnesses,

and their **caregivers**

including family members and providers of care.

PCRC Overarching Strategy

1. Develop **efficient** palliative care **research capacity** nationally.
   - Infrastructure
   - Data systems and procedures
   - Metrics
2. Support the conduct, analysis, and dissemination of **high-quality research** in palliative care.
3. Train and mentor **new, existing, and future clinician-scientists** committed to advancing palliative care research.

A Learning Community

The PCRC is a learning community -- each experience (process, task, interaction etc.) is an opportunity to learn and thereby improve, build upon, and inform future work.

We invite you into this community and welcome your input, suggestions, observations, and participation!

PALLIATIVE CARE RESEARCH COOPERATIVE

Chapter 2: HISTORY AND OVERVIEW

Palliative Care Research Cooperative (PCRC)

- Founded in January 2010
- First research cooperative in the US that focuses specifically on issues relevant to palliative and end of life care (PCEOL)
- Developed infrastructure to provide:
  - methodological resources
  - access to any or all of the PCRC patient populations at PCRC sites
  - a robust network of Palliative Care and End of Life (PCEOL) expert investigators
  - access to PCEOL-related instruments that are standardized and validated and access to standardized operating produces to ensure high quality and ethically sound research
  - Centralized training resources to ensure uniform, quality data collection and streamlined data management strategies.
- Developing informatics infrastructure and interface

Abernethy AP, Aziz NM, Basch E, Bull J, Cleeland CS, Currow DC, Fairclough D, Hanson L, Hauser J, Ko D, Lloyd L, Morrison RS, Otis-Green S, Pantilat S, Portenoy RK, Ritchie C, Rocker G, Wheeler JL, Zafar SY, Kutner JS. *A strategy to advance the evidence base in Palliative Medicine: Formation of a palliative care research cooperative group.* J Palliat Med. 2010; 13(12): 1-7

We are very grateful to the NINR for having the vision to develop a funding mechanism -- NR-14-003 -- and promoting the importance of collaborative palliative care research.

History: Development of the PCRC

Identified Urgent Needs in Palliative Care and End of Life (PCEOL) Research

- Randomized, longitudinal efficacy & effectiveness studies
- Consensus on the most valid and reliable palliative care outcome measures
- Combination of qualitative and quantitative methodologies
- Strategies to ensure ethical treatment of patients as research participants
- Rigorously implement studies and timely disseminate results
- Career development for junior investigators

History: Timing of Events and Milestones that made the development of the PCRC possible

2006 | 2007 | 2008 | 2009 | 2010

- Recognition of hospice and palliative care as a legitimate subspecialty
- Aging population, rising prevalence of chronic illnesses → increased demand
- Historical paucity of research to support practice
- Lack of research capacity
  - data collection, coordinated networks, expertise
  - research workforce
- International models of PC research networks
- IOM report on cooperative groups
- Multiple years of cross-institutional discussion and networking

History: PCRC founded January 2010

Kick-Off Meeting: Denver, Colorado

Accomplishments

- 25 participants
- Commitment to creating PCRC was established
- PCRC core principles were defined
- Approach to developing PCRC was agreed upon
- Proof-of-concept clinical trial (statin study) was outlined
- Timeline developed

Disciplines represented

- Nursing
- Oncology
- Geriatrics
- Neurology
- Cardiology
- Pulmonary
- General Internal Medicine
- Psychology
- Social work
- Public health

Participants represented private and public institutions of academic medicine, schools of nursing, community-based hospice and palliative care, and federal agencies, all with diverse research and clinical interests.

Grant funding through NINR

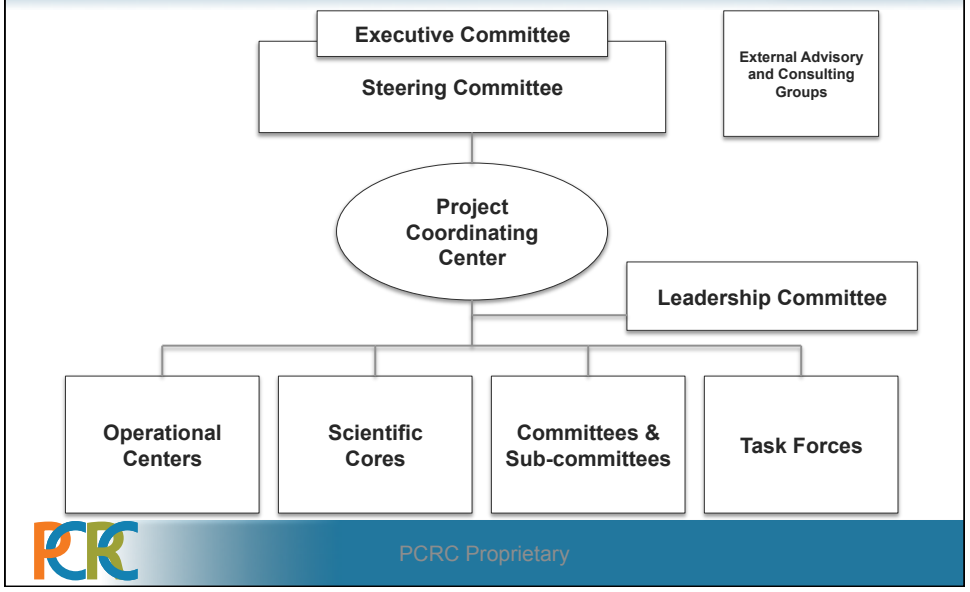
- UC4 award (ARRA Funding): UC4NR12584
  - **Creation and Demonstration of a Palliative Care Research Cooperative Group**
    - 10/1/2010 - 09/30/2013 [3 year]
- U24 award: 1U24NR014637
  - **Enhancing palliative care research capacity through refinement and expansion of the Palliative Care Research Cooperative Group**
    - 10/1/2013 - 06/30/2018 [5 year]

Co-Principal Investigators: Amy Abernethy, MD PhD (Duke)
Jean Kutner, MD, MSPH (UC)

PALLIATIVE CARE RESEARCH COOPERATIVE

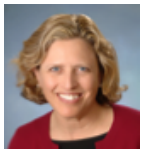
Chapter 3: ORGANIZATIONAL STRUCTURE

Leadership and Organizational Structure



PCRC Executive Committee

Amy Abernethy, MD, PhD
(*Duke University*)
PCRC Co-Chair



Jean Kutner, MD, MSPH
(*University of Colorado*)
PCRC Co-Chair

Christine Ritchie, MD, MSPH
(*University of California San Francisco*)
Chair of the Scientific Review Committee

PCRC Resources and Infrastructure

PCRC Leadership

- Executive Committee**
- Steering Committee

Centralized PCRC Resources

- Project Coordinating Center
- Investigator Development Center (IDC) **

Active Task Forces

- Face-to-Face Investigator Meeting Planning Task Force

Core Resources

- Data, Informatics & Statistics Core (DISC) **
- Caregivers Research Core **
- Clinical Studies Core **
- Measurement Core **

Active Committees

- Scientific Review Committee **
- Membership Committee **

*** Directors also serve on the Leadership Committee Group*

Project Coordinating Center

Co-Directors: Amy Abernethy, MD PhD & Jean Kutner, MD MSPH

- **Study development**: grant development, grant writing, protocol development, concept review
- **Study conduct**: training, quality assurance, data management (study operations)
- **Study management**: administration, finance, grant management, performance monitoring, reporting
- **Coordination** within and between studies, participants, investigators, patient advocates, and sites, and between these stakeholders and the PCRC itself: communication, site development, website
- **Dissemination**: planning, training, writing, and using other means to increase visibility of PCRC findings

Investigator Development Center (IDC)

Director: Christine Ritchie, MD MSPH

- Oversee a multi-faceted approach to workforce development for PCEOL research, in a way that both leverages and collaborates with the resources and infrastructure offered by the PCRC
- Provide investigator development initiatives using various educational didactics
- Facilitate and identify mentorship relationships between senior mentors and researchers new to PCEOL research or types of research (e.g., industry trials, collaborating with the VA)
- Collaborate with the National Palliative Care Research Center to synergize training activities
- Provide resources and expertise to junior PCEOL investigators

Data, Informatics and Statistics Core (DISC)

Director: Greg Samsa, PhD

Lead Statistician: Patrick (Jud) Blatchford, PhD

- Provide support to investigators, sites, studies, and the PCRC as a whole in the statistical and data-related aspects of trial design, evaluation, quality assurance, data analysis/reporting, and data sharing
- Provide IT and clinical informatics support (e.g., standardized electronic data collection methodologies)
- Create interoperable data elements (variables) and core measures (instruments / questionnaires)
- Align with and incorporate data-related methods used in important national initiatives
- Integrate information from electronic health records (EHRs)

Caregivers Research Core

Director: Betty Ferrell, PhD RN
Sub-Investigator: Elaine Wittenberg, PhD

- Advance caregiver research by providing resources and expertise to PCRC investigators & other PCEOL researchers
- Coordinate closely with other PCRC cores in identifying preferred study designs, measures, and instruments that address the spectrum of relevant PCEOL caregiver outcomes
- Elevate the quality and prominence of caregiver research by providing expertise in the vetting and conduct of caregiver studies developed with and/or by the PCRC
- Identify priority gaps in PCEOL caregiver research and provide direction to investigators conducting research that addresses these gaps, thereby advancing the field

Clinical Studies Core

Director: Francis Keefe, PhD
Sub-Investigator: Tammy Somers, PhD

- Prepare guidance materials and methods that are standardized and available, and are relevant to PCEOL interventions, clinical trials, and bio-behavioral outcomes
- Provide expertise to assist investigators in developing novel studies and respond promptly to funding announcements and other emerging opportunities
- Connect investigators to consultants (including PCRC experts) who can work closely with investigators to develop high-quality PCEOL studies
- Incorporate novel approaches into PCEOL studies, such as bio-behavioral interventions for symptom management
- Provide guidance in appropriate study design (matched to research question)

Measurement Core

Director: Ethan Basch, MD MSc
Sub-Investigator: Antonia Bennett, PhD

- Provide advice to PCRC and other PCEOL investigators regarding study measures and study-specific challenges
- Develop new measures relevant to PC populations:
  - measurement tools appropriate for populations with changing and declining cognition;
  - tools for measuring quality-of-life among caregivers of PCEOL patients; and
  - instruments appropriate for use in people with multiple co-morbid conditions.
- Provide centrality of outcomes, measures, and metrics in study conceptualization, design, conduct, and analysis

PCRC Leadership *[Feb 2015]*

Steering Committee


Amy Abernethy
Duke Univ


Jean Kutner
Univ of Colorado


Christine Ritchie
UCSF


Marie Bakitas
UAB


Janet Bull
Four Seasons


Betty Ferrell
City of Hope


Laura Hanson
UNC


Steve Pantilat
UCSF


Greg Samsa
Duke Univ


Charles von Gunten
Ohio State


Jeri Miller
NINR

Steering Committee Responsibilities

- Provide organizational leadership and guide scientific development in line with advances in the field and the needs for innovation.
- Monitor organizational and research progress, and make decisions regarding change in infrastructure, resource allocation, and scientific directions.
- Facilitate communication and collaboration across the PCRC and with external stakeholders.
- Fiduciary responsibilities include fiscal management and oversight, ensuring that the PCRC is sustainable with a sound business approach, and minimal conflicts of interest.
- Oversee data operations and reliable research results.
- Ensure compliance and conduct of high quality trustworthy research.

PCRC Operations Team

- Trial Management
- Site Training
- Site Development

Rachael Bennett
Univ of Colorado

- Protocol Development
- Research Coordination

Carey Candrian
Univ of Colorado

- Communication
- Website
- Meetings & logistical coordination

Jordan Lodato
Duke Univ

- Data Management and Statistics
- Trial Specific Issues

Jud Blatchford
Univ of Colorado

- Administrative
- General Group Issues

Molly Gavigan
Duke Univ

- Finance
- Budgets
- Contracts

Lynnette Thacker
Duke Univ

** Please see Appendix for Contact Information

PALLIATIVE CARE RESEARCH COOPERATIVE

Chapter 4: MEMBERS

PCRC Membership

- Membership is open to healthcare providers and researchers of *any discipline* who:
  - focus on the care of persons with advanced and/or life-limiting illness and of their family members, caregivers, and other loved ones;
  - share a dedication to improving care and outcomes for this population through rigorous research; and
  - actively participate in advancing the science and developing the evidence base to support palliative care
- PCRC membership is reviewed annually by the Membership Committee and benchmarked according to PCRC membership performance metrics
- If you change institutions/locations your individual PCRC membership transitions with you.
- Please refer to the Membership Guidelines for specific details of membership.

Types of Individual Membership

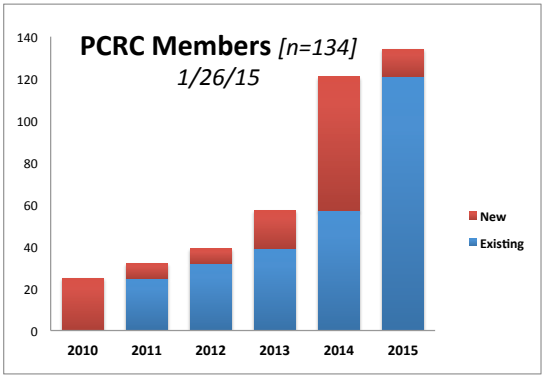
Membership within the PCRC is defined at the individual member level. There are three categories of membership:

- Full Member
- Junior Investigator Member
- Affiliate Member

The Institution / Organization with which a PCRC member is affiliated is instrumental in the success of the PCRC. These organizations support Individual member(s) in attaining professional goals, and / or they contribute to the PCRC's research mission by allowing for and facilitating the conduct of PCRC studies at that organizational location.

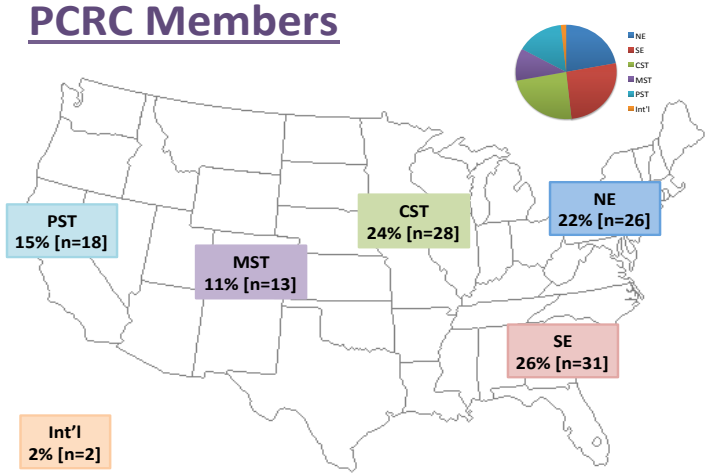
Membership Metrics – 1/26/2015

Individual Members	Active
Full Members	70
Junior Investigators	54
Affiliate Members	10
TOTAL	134



Membership Metrics – 1/26/2015

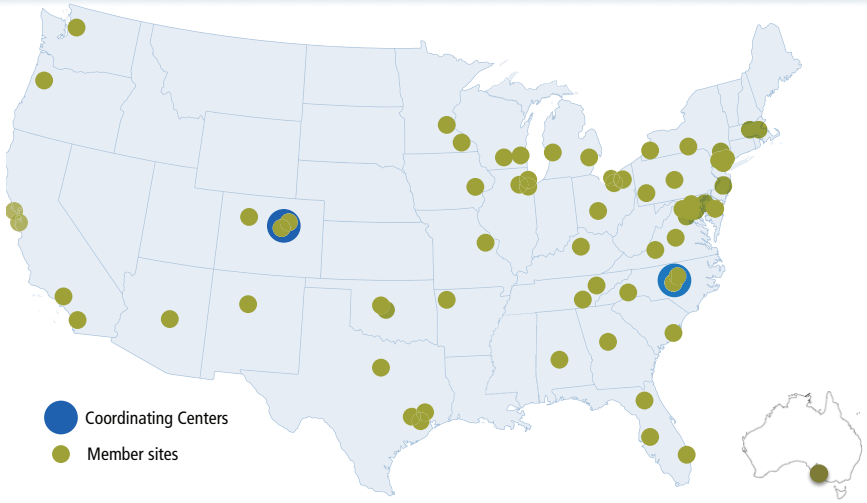
PCRC Members



PCRC Proprietary

Location of Individual Members' Organization / Institution of Record **

As of 1/26/15



PCRC Proprietary

Diversity Includes SON, SPH, CCC, minority patient populations

Listing of Individual Members' Organization of Record (n=64)

As of 1/26/15

Site / Affiliation	City	St	N	Site / Affiliation	City	St	N
Baylor University	Houston	TX	2	Rush University	Chicago	IL	2
Binghamton University	Binghamton	NY	1	Salisbury University	Salisbury	MD	1
Capital Caring	Falls Church	VA	3	Seasons Hospice & Palliative Care	Rosemont	IL	1
Case Western Reserve University	Cleveland	OH	1	Stanford University	Stanford	CA	1
Center for Hospice & Palliative Care	Buffalo	NY	1	The Denver Hospice	Denver	CO	1
Chapters Health System	Lakeland	FL	1	The Medical University of South Carolina	Charleston	SC	3
Children's Hospital & Clinics of Minnesota	Minneapolis	MN	1	Trillium Institute	Grand Rapids	MI	1
City of Hope Medical Center	Duarte	CA	4	TrustBridge Health, Inc.	Fort Lauderdale	FL	1
Cleveland Clinic	Cleveland	OH	3	Univeristy of Florida	Gainesville	FL	2
Duke University	Durham	NC	13	University of Alabama at Birmingham	Birmingham	AL	5
Emory University	Atlanta	GA	1	University of Arkansas for Medical Sciences	Fayetteville	AR	1
Flinders University	Daw Park	AUS	2	University of California San Diego	La Jolla	CA	1
Fordham University	New York	NY	1	University of California San Francisco	San Francisco	CA	9
Four Seasons	Flat Rock	NC	1	University of Colorado	Denver	CO	10
George Washington University	Washinton	DC	1	University of Iowa	Iowa City	IA	2
Hospice of Chattanooga	Chattanooga	TN	1	University of Maryland Baltimore	College Park	MD	5
Hospice of Chesapeake	Annalopis	MD	1	University of Massachusetts	Worcester	MA	1
Hospice of the Bluegrass	Lexington	KY	1	University of New Mexico	Albuquerque	NM	1
Hospice of the Western Reserve	Cleveland	OH	1	University of North Carolina at Chapel Hill	Chapel Hill	NC	3
Johns Hopkins	Baltimore	MD	1	University of Oklahoma	Norman	OK	2
Kaiser Permamente Colorado	Denver	CO	1	University of Pittsburgh	Pittsburgh	PA	2
Massachusetts General Hospital	Boston	MA	1	University of Tennessee	Knoxville	TN	1
Mayo Clinic	Rochester	MN	2	University of Virginia	Charlottesvile	VA	1
MD Anderson	Houston	TX	1	University of Washington	Seattle	WA	3
Medical College of Wisconsin	Milwaukee	WI	2	University of Wisconson - Madison	Madison	WI	2
MJHS Institute for Innovation in Palliative	New York	NY	1	UT Houston	Houston	TX	1
Mount Sinai Medical Center	New York	NY	1	UT Southwestern Medical Center	Dallas	TX	1
New York University	New York	NY	1	VA New Jersey Health Care System	East Orange	NJ	1
Northwestern University	Chicago	IL	4	Virginia Commonwealth University	Richmond	VA	2
Ohio State University	Columbus	OH	1	Washinton University	St Louis	MO	3
Oregon State University	Corvallis	OR	1	Wayne State Univeristy	Detroit	MI	1
Penn State University	State College	PA	1				
Phoenix VA Health Care System	Phoenix	AZ	2	Private/Currently Unaffiliated			3

PALLIATIVE CARE RESEARCH COOPERATIVE

Chapter 5: GENERAL INFORMATION

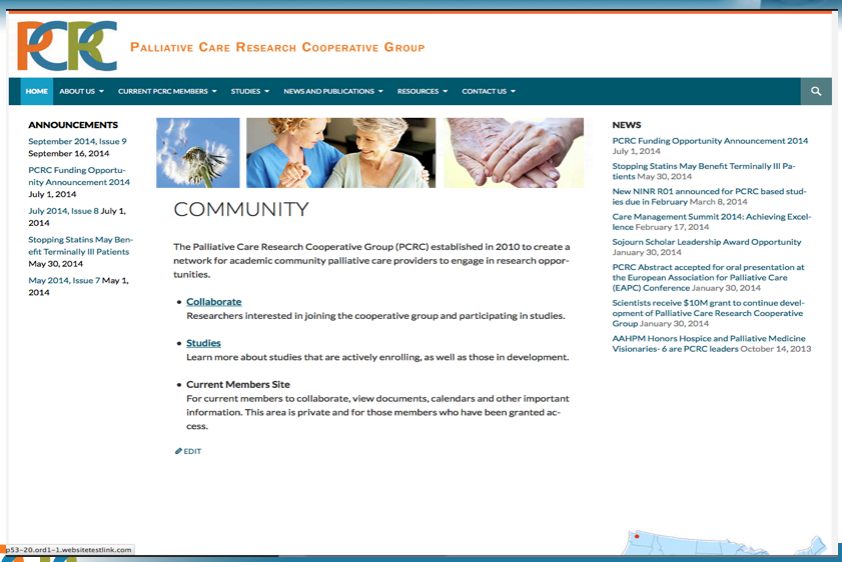
PCRC Website
Palliativecareresearch.org

- Current website is accessible to general public
- Includes additional information regarding:
  - Membership application and current membership roster
  - Active PCRC studies
  - Related publications
  - Charter
  - Mission and Vision Statements
  - Resources and Infrastructure
  - Overview of Centers and Cores
  - Funding Opportunities and Grant Resources
  - Newsletters and Announcements

Evolution of the PCRC Website

- We are growing, expanding and evolving!
- The PCRC website is a work in progress -- we welcome suggestions for content, format, and information that you would like access to on the website.
- Our vision for the website is to:
  - foster an online community, and
  - be the hub where investigators obtain all PCRC-related information, including study-specific documents, news updates, relevant documents and manuscripts, and answers to questions.
- Help us maintain a website that is useful to all members!

PCRC Website Home Page

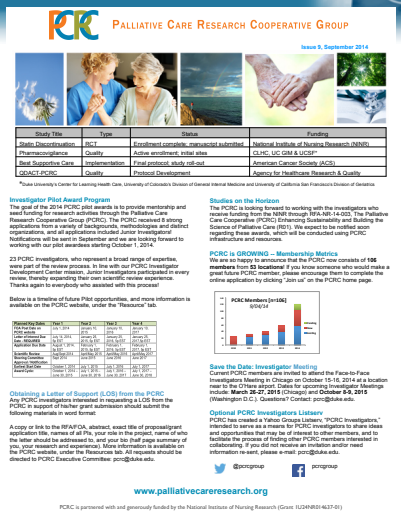


Core Measures & Core Data Elements Library

- Standardized formats
  - Commonly used forms such as enrollment, demographics, and baseline clinical data.
- Common forms library
  - Includes survey instruments to measure concepts such as: symptoms, pain, health related quality of life, depression, coping, well-being, self-efficacy, satisfaction with care, and caregiver burden
- Library of PCRC-preferred common data elements
  - Provide recommendations for elements in use / existence that are relevant and applicable to be cost effective and allow for multi-study data analysis. For example, the Edmonton Symptom Assessment Scale is our preferred basic symptom inventory instrument.
- Forms and data elements are being transferred into common data formats and web-based data forms / data entry systems

Communication: A variety of modalities

- Email distributions
- Newsletters (disseminated every other month)
- Website: ongoing updates
- Meetings
- Teleconferences
- Social Media
- Member Listserv
- Web-based training for new study rollout



PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

Issue 9, September 2014

Study Title	Type	Status	Funding
Statin Discontinuation	RCT	Enrollment complete, manuscript submitted	National Institute of Nursing Research (NINR)
Pharmacovigilance	Quality	Active enrollment; initial sites	CLHC, UC GIM & UCSF*
Best Supportive Care	Implementation	Final protocol; study roll-out	American Cancer Society (ACS)
UDACT-PCRC	Quality	Protocol Development	Agency for Healthcare Research & Quality

*Duke University's Center for Learning Health Care, University of Colorado's Division of General Internal Medicine and University of California San Francisco's Division of Geriatrics

Investigator Pilot Award Program

The goal of the 2014 PCRC pilot awards is to provide mentorship and seed funding for research activities through the Palliative Care Research Cooperative Group (PCRC). The PCRC received 8 strong applications from a variety of backgrounds, methodologies and distinct organizations, and all applications included Junior Investigators! Notifications will be sent in September and we are looking forward to working with our pilot awardees starting October 1, 2014.

23 PCRC investigators, who represent a broad range of expertise, were part of the review process. In line with our PCRC Investigator Development Center mission, Junior Investigators participated in every review, thereby expanding their own scientific review experience. Thanks again to everybody who assisted with this process!

Below is a timeline of future Pilot opportunities, and more information is available on the PCRC website, under the "Resource" tab.

Planned Key Dates	Year 1	Year 2	Year 3	Year 4
First Full Call for PCRC website	July 1, 2014	January 1, 2015	January 1, 2016	January 1, 2017
Letter of Intent Due Date - REQUIRED	July 15, 2014	January 15, 2015	July 15, 2015	January 15, 2016
Application Due Date	August 1, 2014, 5PM	February 1, 2015	August 1, 2015	February 1, 2016
Scientific Review Meeting/Committee	September 2014	March 2015	September 2015	March 2016
Anticipated Award Date	October 1, 2014	May 1, 2015	October 1, 2015	May 1, 2016
Anticipated Award Date	October 1, 2014 - June 30, 2015	May 1, 2015 - June 30, 2016	October 1, 2015 - June 30, 2017	May 1, 2016 - June 30, 2018

Obtaining a Letter of Support (LOS) from the PCRC

Any PCRC investigators interested in requesting a LOS from the PCRC in support of his/her grant submission should submit the following materials in word format:

A copy or link to the RFA/FOA, abstract, exact title of proposal/grant application title, names of all PIs, your role in the project, name of who the letter should be addressed to, and your bio (half page summary of you, your research and experience). More information is available on the PCRC website, under the Resources tab. All requests should be directed to PCRC Executive Committee: pcrc@duke.edu.

Studies on the Horizon

The PCRC is looking forward to working with the investigators who receive funding from the NINR through RFA-NR-14-003, "The Palliative Care Cooperative (PCRC) Enhancing Sustainability and Building the Science of Palliative Care (R01). We expect to be notified soon regarding these awards, which will be conducted using PCRC infrastructure and resources.

PCRC is GROWING – Membership Metrics

We are so happy to announce that the PCRC now consists of **106 members** from **53 locations**! If you know someone who would make a great future PCRC member, please encourage them to complete the online application by clicking "Join us" on the PCRC home page.

Save the Date: Investigator Meeting

Current PCRC members are invited to attend the Face-to-Face Investigators Meeting in Chicago on October 15-16, 2014 at a location near to the O'Hare airport. Dates for upcoming Investigator Meetings include: **March 26-27, 2015** (Chicago) and **October 8-9, 2015** (Washington D.C.). Questions? Contact: pcrc@duke.edu.

Optional PCRC Investigators Listserv

PCRC has created a Yahoo Groups Listserv, "PCRC Investigators," intended to serve as a means for PCRC investigators to share ideas and opportunities that may be of interest to other members, and to facilitate the process of finding other PCRC members interested in collaborating. If you did not receive an invitation and/or need information re-sent, please e-mail: pcrc@duke.edu.

@pcrcgroup pcrcgroup

www.palliativecareresearch.org

PCRC is partnered with and generously funded by the National Institute of Nursing Research (Grant: 1U2NR014637-01)

Contact / Network

Palliative Care Research Cooperative Group [PCRC]

palliativecareresearch.org

@pcrcgroup

pcrcgroup

pcrc@duke.edu

Meetings

- Face-to-Face Investigator Meetings**:
  - Semi-annual, each Spring & Fall (1-2 day meeting)
- Investigator Teleconferences
  - Every other month [2nd Monday, 11-12 am EST]
- Study-specific Learning Community Teleconferences with Clinical Research Coordinators (CRCs)
  - Schedule per study, involved sites
- Study/ Project-Specific Teleconferences
  - Schedule per study, involved sites

 ** Described in more detail in Chapter 6

PALLIATIVE CARE RESEARCH COOPERATIVE

Chapter 6: RESEARCH

Need help with multi-site research?

The PCRC was established in large part to help overcome the many challenges of multi-site research because we know this research matters and is necessary to advance the field of palliative care.

STEPS OF THE PROCESS:

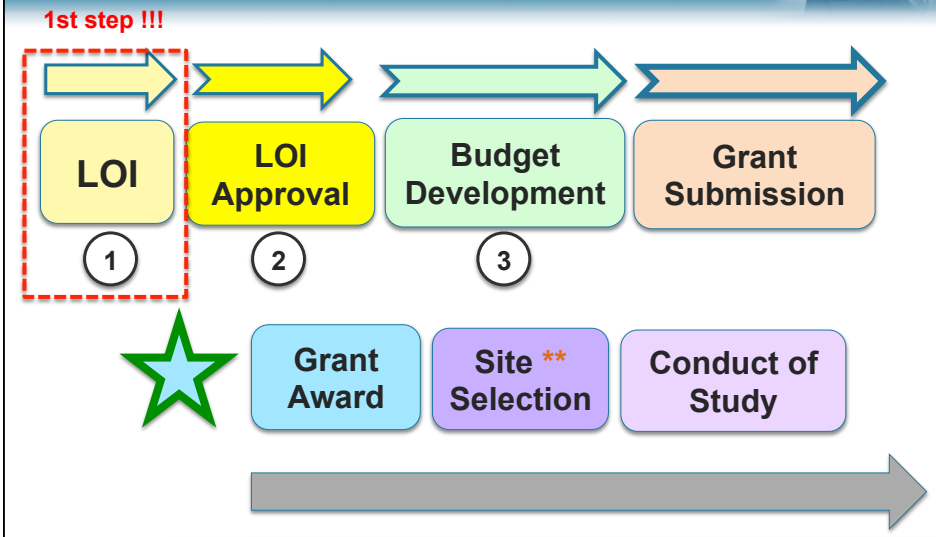
① Submit a Letter of Intent (LOI) to the PCRC Scientific Review Committee (SRC) **

② Approval of the LOI at the PCRC Steering Committee level

③ Budget Development (after LOI approval)

** See PCRC website for instructions and additional details.

Overview



** NOTE: Final sites are NOT selected until grant is awarded

PCRC Study Development

There are 5 steps involved in developing, approving & rolling out a new PCRC protocol:

- Step 1: Letter of Intent (LOI) Submission and Review
- Step 2: Protocol Development (and related documents)
- Step 3: Statistics/Informatics Development
- Step 4: Site Selection Process and Roll-out
- Step 5: Start-up/Training

** also available on PCRC website

Online Resources & Information

PCRC Investigator Support

- PCRC supports investigators' research and studies by:
  - Taking research questions from concept to study design
  - Providing replicable research infrastructure
  - Developing a comprehensive protocol & study-specific materials
  - Training site-based study personnel
  - Assisting with enrollment initiation
  - Ensuring high quality data collection
  - Providing regular tracking of performance metrics
  - Supporting publication of findings in accordance with the PCRC Authorship Protocol to advance the quality & impact of Palliative Care and End of Life (PCEOL) research

Site Selection for funded studies

NOTE: **Site selection is performed AFTER grant award**

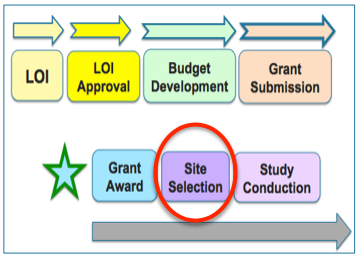
Steps:

① LOI/protocols are approved by the SRC and Steering Committee

② Project is funded [Grant is awarded]

③ PCRC will match site capabilities and potentially available study populations with the needs of the study.

- Presently, the PCRC has 64 different organizations where our individual members reside {*representing diverse patient populations including cancer and non-cancer life-limiting illnesses, diverse racial and ethnic groups, academic and community settings, hospice and palliative care settings, and diverse site research team methodological experience.*}
- More sites will be included in the future.



Site Selection for funded projects

NOTE: **Site selection is performed AFTER grant award**

***Exception: Study PI's site*

Rationale: ***Match studies with Study Site Principal Investigators (SSPIs) / sites to optimize accrual***

- Match with the most up-to-date list of sites and SSPIs
- Because we don't know **which** studies / grants are going to get funded **when**, this allows us to balance the number of studies at any particular site (and reduce the chance that a single site gets overwhelmed)
- Enhances prioritization of your study at a site

Site Selection Process (funded projects)

- Review study specifics: the number of sites required for enrollment needs is determined by:
  - Statistical Analysis Plan (SAP)
  - Planned budget
- Review PCRC Membership Database for potential
  - Subject population
  - SSPI (study site PI) and Site expertise
- Interest-feasibility [I-F] request sent to ~3x # needed.
- Review of returned I-F forms with Study PI
  - may need to recruit outside of PCRC membership
- Final Site selection decisions.
- Site and Study start-up processes

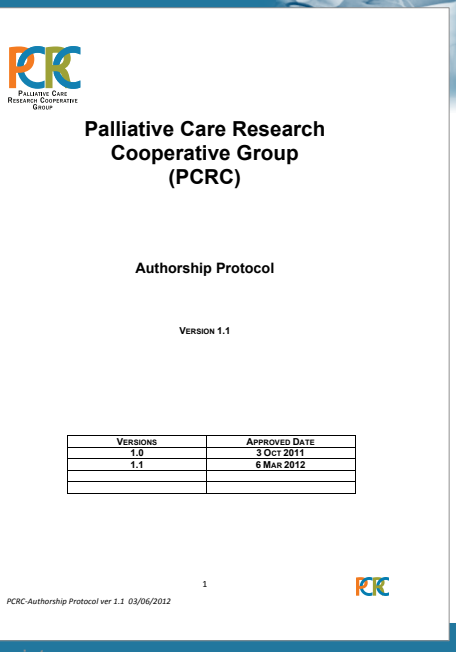
PCRC Studies

Title	Type	Status	Funding
Statin Discontinuation	Randomized Control Trial	Closed; Manuscript in press *(Mar 2015)*	NINR UC4 *(National Institute of Nursing Research)*
Pharmacovigilance	Quality	Active Enrollment	CLHC, UC GIM & UCSF*
Best Supportive Care	Implementation	Active Enrollment	ACS *(American Cancer Society)*
QDACT PCRC Feasibility	Quality	Active Enrollment	AHRQ *(Agency for Healthcare Research & Quality)*
Pancreatic Care Planning	Intervention	Active Enrollment	PCRC Pilot Award
Anticoagulation Therapy	Retrospective Cohort	Active Enrollment	PCRC Pilot Award
Statin Guidelines & Practice Patterns	Survey	Active Enrollment	PCRC Pilot Award
Family Experiences of ICU Transfer	Prospective Interview	Active Enrollment	PCRC Pilot Award
CG Assisted Pain Management	RCT	Active Enrollment	NINR R01
Pediatric Social Support	Intervention	Active Enrollment	NINR R01
CG Support for Pts w. Lung Cancer	Intervention	Active Enrollment	NINR R01
*** 6 Pilot Awards Pending			

* Duke University's Center for Learning Health Care, University of Colorado's Division of General Internal Medicine and University of California San Francisco's Division of Geriatrics

Authorship Protocol

- Full document available on PCRC website
- Each Study Start-Up Meeting will include a discussion of publication and authorship expectations



Palliative Care Research Cooperative Group

Palliative Care Research Cooperative Group (PCRC)

Authorship Protocol

VERSION 1.1

VERSIONS	APPROVED DATE
1.0	3 OCT 2011
1.1	6 MAR 2012

1

PCRC-Authorship Protocol ver 1.1 03/06/2012

Authorship: Minimum Criteria

- Authorship = substantial participation; all of the following conditions are met:
  - Conception and design, or analysis and interpretation of data, or both,
  - Drafting the article or revising it critically for important intellectual content,
  - Final approval of the version of the manuscript to be published.
- Participation solely in the following does NOT guarantee authorship
  - acquisition of funding,
  - general supervision of the research group,
  - collection of data.
- One co-author will be nominated as Executive Author
- Signed authorship statements
  - acknowledges each author's contribution in writing and includes the order of authors.

Authorship Declaration

Three areas of contribution to the manuscript are included:

At least 1 of the 3 below:

- Conception and design
- Acquisition of data
- Analysis and interpretation of data

At least 1 of 2 below:

- Drafting of the manuscript
- Critical revision of the manuscript for important intellectual content

At least 1 of below:

- Statistical analysis
- Obtaining funding
- Administrative, technical, or material support
- Supervision
- No addition contributions
- Other (specify)

PCRC Letters of Support (LOS) **

***** See PCRC website for instructions and additional details.***

To demonstrate mutual collaboration to work together, all LOS include language for which collaborators agree to adhere:

- To follow PCRC standards & processes in their project including Use of Measurement Instruments & Standard Data Elements, Participation in Study Participant Registry, Data Sharing Agreements, & Financial Management Processes;
- That all Letters of Intent (LOI) and protocols will be reviewed by the PCRC Scientific Review Committee to ensure highest methodological standards;
- That all publications will adhere to the PCRC authorship guidelines to ensure consistent approaches to assigning authorship; and
- To adhere to PCRC Conflict of Interest and Code of Conduct practices, in the interest of ensuring transparent and trustworthy research.

PALLIATIVE CARE RESEARCH COOPERATIVE

Chapter 7: MEMBER OPPORTUNITIES

Member Privileges and Opportunities **

- Participate in voting as a member of your affiliated institution.
- Consider serving as a Study and/or Study Site PI
- Participate in PCRC Investigator and PCRC Business Meetings
- Serve on PCRC committees
- Engage in PCRC research
- Propose scientific and research concepts to the PCRC for consideration
- Contribute to PCRC publications
- Receive PCEOL research mentorship
- Receive / give mentorship to other investigators

** See your specific membership letter for details

Expectations **

- Abide by PCRC operating procedures, including adherence to study protocols and authorship protocol
- Be responsive to needs/requests of the Steering Committee and PCRC Executive Team in an efficient manner
- Participate in at least 1 PCRC Face-to-Face Investigator Meeting every 3 years
- Demonstrate commitment to the PCRC by:
  - participating as an active committee member, or
  - contributing to the scientific development of PCRC by providing expertise, or
  - contributing to clinical studies through study development or conduct
- Complete annual self-reporting activities when requested
- Complete a PCRC Conflict of Interest (COI) report when requested

** See your specific membership letter for details

Semi-Annual Investigator Meetings

The PCRC Investigators meet every spring and fall to get updates, share ideas, conduct PCRC business functions, and discuss ways to collaborate.

Announcements regarding the time and location of the meetings are sent months in advance. Please plan to attend and participate – these are a great way to foster your professional relationships with people of like minds.

Stay Informed

- Check in with the PCRC by visiting the website on a regular basis. As mentioned before, we anticipate a dynamic online community, with the website serving as the centralized hub of information dissemination
- Foster connections made during semi-annual Face-to-Face Investigator Meetings
- Identify ways to collaborate with others
- Bring study ideas forward to the PCRC SRC for consideration and review

PALLIATIVE CARE RESEARCH COOPERATIVE

APPENDIX

Questions? Contact names and numbers

WHO TO CONTACT - PCRC OPERATIONS			
AREA	*WHO*	*PHONE*	*EMAIL*
Group Leadership / Grants / Committees	**Amy Abernethy**	919-668-0647	*amy.abernethy@duke.edu*
Group Leadership / Grants / Committees	**Jean Kutner**	303-724-2240	*jean.kutner@ucdenver.edu*
New Research Ideas / Scientific Review / Investigator Training	**Christine Ritchie**	415-476-0605	*christine.ritchie@ucsf.edu*
Membership	**Janet Bull**	828-233-0302	*jbull@fourseasonscfl.org*
Trial Management / Data Collection & Quality / Training / Site Development	**Rachael Bennett**	303-724-6561	*rachael.bennett@ucdenver.edu*
Data Management / Statistical Trial Specific Issues	**Jud Blatchford**	303-724-4352	*patrick.blatchford@ucdenver.edu*
Protocol Development / Research Coordination	**Carey Candrian**	303-724-7892	*carey.candrian@ucdenver.edu*
Administrative / Regulatory-Legal / General Group issues	**Molly Gavigan**	919-668-8717	*molly.gavigan@duke.edu*
Communication [Website, Newsletter, etc.] /Meetings & logistical coordination / Membership inquiry	**Jordan Lodato**	919-684-0257	*jordan.lodato@duke.edu*
Budget / Contracts	**Lynnette Thacker**	919-668-0352	*lynnette.thacker@duke.edu*
Website: www.palliativecareresearch.org			