PALLIATIVE CARE
RESEARCH COOPERATIVE

New Member Orientation

Version Date: May 6, 2014

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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.

Regardless of your familiarity with the research cooperative model, undoubtedly you will have specific questions about how we work.

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!

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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

Urgent Needs – 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

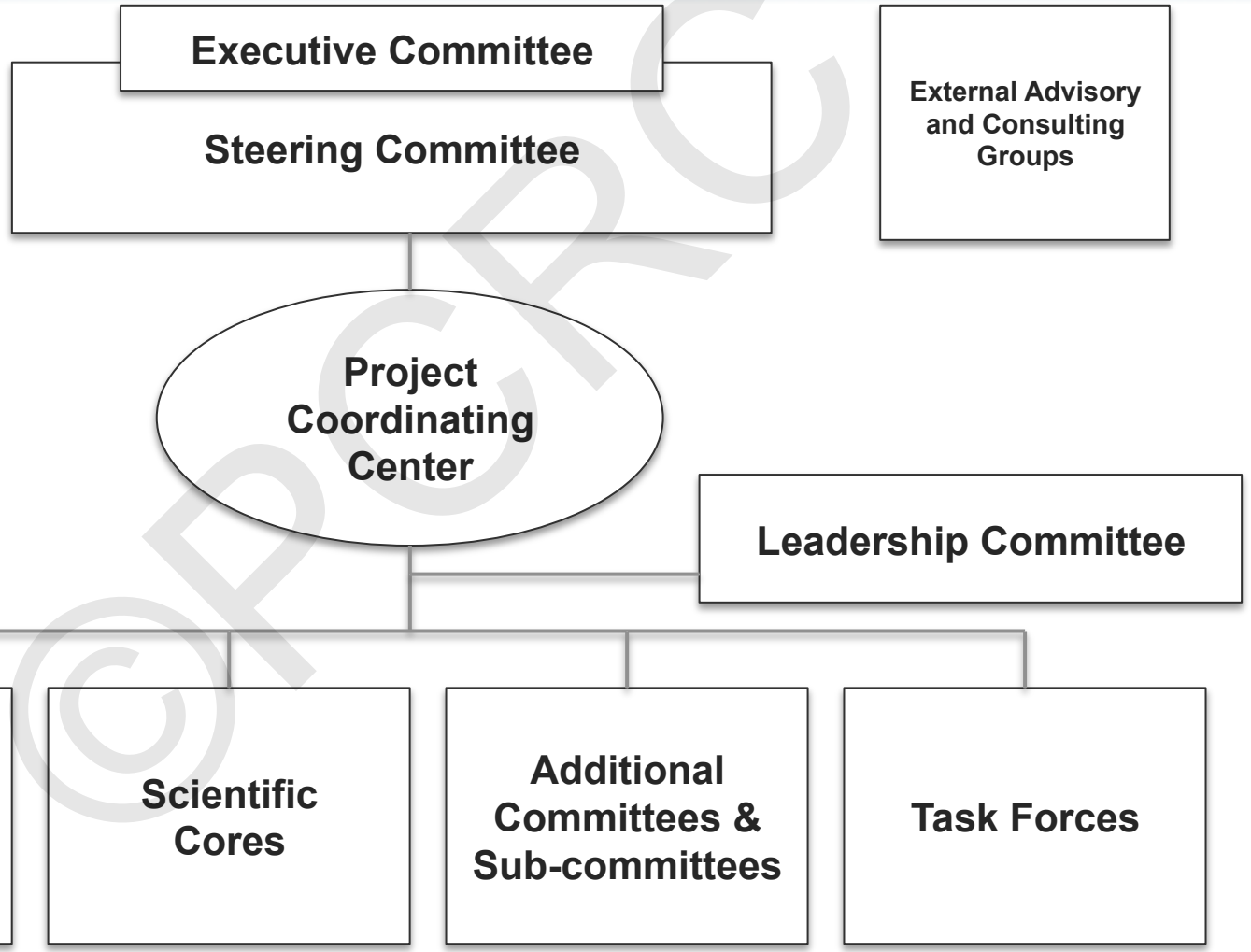
- UC4 award (ARRA Funding): UC4NR12584
  - **Creation and Demonstration of a Palliative Care Research Cooperative Group**
    - 10/1/2010 - 09/30/2013 [3 year]
- U24 award: 1U24NR014637
  - **Enhancing palliative care research capacity through refinement and expansion of the Palliative Care Research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

Centralized PCRC Resources

- Coordinating Center
  - General Operations
  - Communications
  - Protocol Development
  - Site Management
- Investigator Development Center (IDC)

Core Resources

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

Active Committees

- Executive Committee
- Steering Committee
- Scientific Review Committee
- Membership Committee

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 structured mentorship using various teaching modalities
- Facilitate and identify mentorship relationships between senior mentors and experienced 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: Virginia Sun, PhD RN

- 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 (Frank) 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

Steering Committee

Amy Abernethy
Duke Univ

Jean Kutner
Univ of Colorado

Christine Ritchie
UCSF

Janet Bull
Four Seasons

Diane Fairclough
Univ of Colorado

Betty Ferrell
City of Hope

Laura Hanson
UNC

Susan Marden
NINR

Steve Pantilat
UCSF

Charles von Gunten
Ohio State

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.
- Provide 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 **

Rachael Bennett
Univ of Colorado

* Site Coordination
* Site Training
* Trial Data / Quality

Carey Candrian
Univ of Colorado

* Protocol Development
* Site Development

Jordan Lodato
Duke Univ

* Communication
* Website
* Newsletter
* Meetings & logistical coordination

Jud Blatchford
Univ of Colorado

* Data Management & Statistical Trial Specific Issues

Molly Gavigan
Duke Univ

* Administrative
* General Group Issues

Lynnette Thacker
Duke Univ

* Finance
* Budgets
* Contracts

** Please see Appendix for Contact Information

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Chapter 4: TEAM

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 key performance metrics
- Please refer to the Membership Guidelines for specific details of membership.

Types of Individual Membership

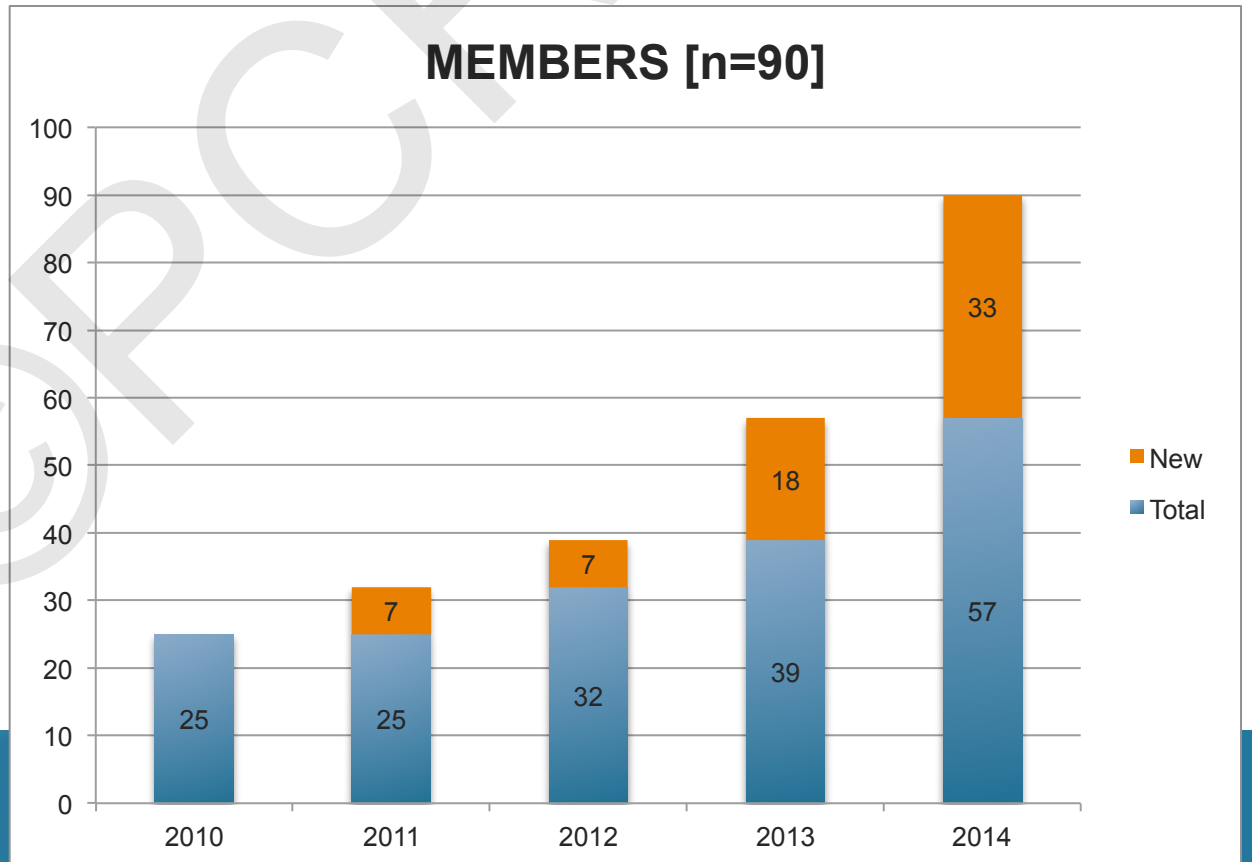
Membership within the PCRC is defined at the Individual member level. There are three categories of membership:

- Full Member
- Junior Investigator
- Affiliate Member

The Organization with which a PCRC member is affiliated is instrumental in the success of the PCRC. Multiple sites might be part of one organization. These sites 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 site.

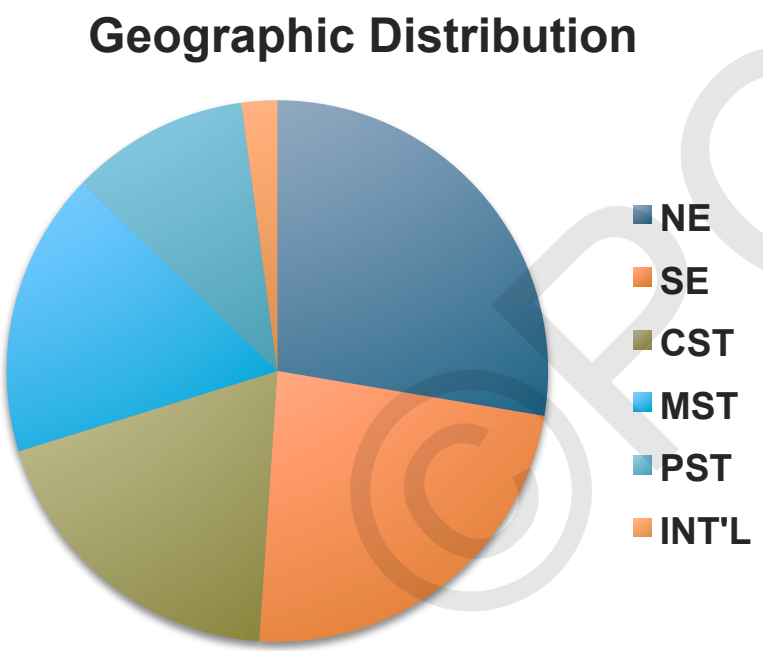
Membership Metrics – 4/22/14

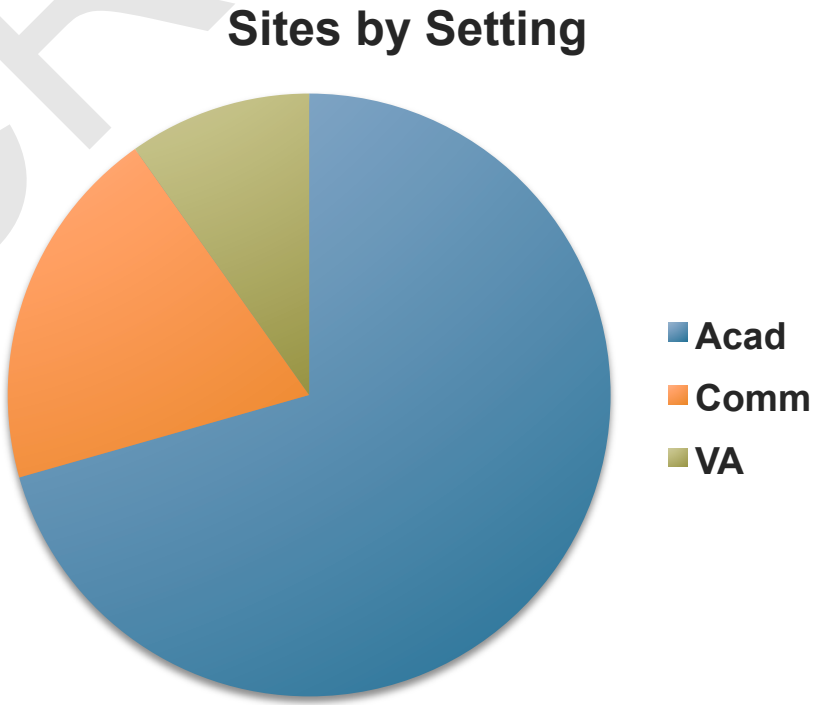
Individual Members	*Active*
* Full Members	50
* Junior Investigators	34
* Affiliate Members	6
TOTAL	**90**



Membership Metrics – 4/22/14

47 locations



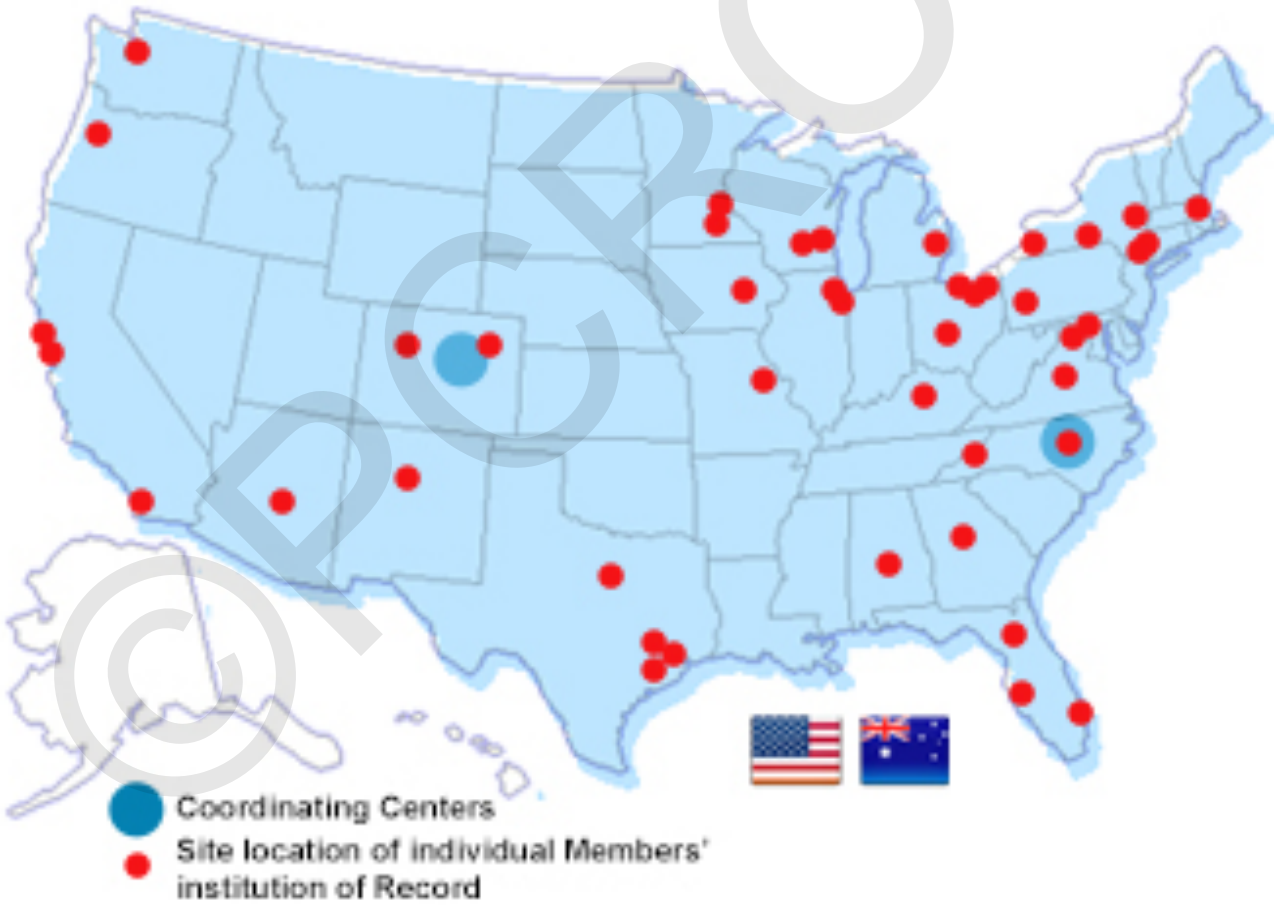


Individual Members' Institution of Record [n=47] **

- University of Colorado
- Duke University
- Four Seasons
- University of North Carolina Chapel Hill
- University of Alabama Birmingham
- Beth Israel
- University of Wisconsin Madison
- Northwestern University
- Mayo Clinic
- Mount Sinai
- **PACCSC**
- Kaiser Permanente Colorado
- Case Western Reserve University
- Washington University St Louis
- Capital Caring
- University of California San Francisco
- City of Hope
- Ohio State University
- MDACC
- The Denver Hospice
- Hayden Medical Center
- University of Washington
- Binghamton University
- Cleveland Clinic
- Emory University
- New Jersey VA
- Stanford University
- University of Massachusetts
- University of New Mexico
- University Texas Southwestern
- Virginia Commonwealth University
- Wayne State University
- Hospice of Western Reserve
- Children's Hospital & Clinics of Minnesota
- Buffalo Hospice
- Texas Children's Hospital / Baylor
- Rush
- University of Maryland
- Hospice of Palm Beach & Broward Counties
- University of Florida
- University of Pittsburgh
- Medical College of Wisconsin
- Chapters Health Center
- University of Texas Houston
- University of Iowa
- Hospice of the Bluegrass
- Oregon Health & Science University

***Diversity Includes SON, SPH, CCC, minority patient populations*

Site Location of US Individual Members' Institution of Record (n=47 US sites) **



**Diversity Includes SON, SPH, CCC, minority patient populations

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Chapter 5: GENERAL INFORMATION

PCRC Website (as of January 2014):

Palliativecareresearch.org

- Current website is accessible to general public
- Content currently includes:
  - Membership application, member roster and membership type
  - Active studies
  - Related publications
  - Charter
  - Mission and Vision Statements
  - Newsletters and Announcements

FUTURE: Members Only website: Launching time: TBD

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 craft a website that is useful to all members!

Website homepage (next slide)


PCRC
Palliative Care Research Cooperative Group
Search Site
This section only
Home
About Us
Members
Studies
Events
News / Pubs
Resources
Membership Application
Patients and Families
Members Site
Palliative Care Links
COMMUNITY
The Palliative Care Research Cooperative Group (PCRC) established in 2010 to create a network for academic community palliative care providers to engage in research opportunities.
Collaborate
Researchers interested in joining the cooperative group and participating in studies.
Studies
Learn more about studies that are actively enrolling, as well as those in development.
Current Members Site
For current members to collaborate, view documents, calendars and other important information. This area is private and for those members who have been granted access.
Join Us
Develop scientifically-based methods that lead to meaningful evidence for decreasing the suffering of patients with advanced or potentially life limiting illnesses and their caregivers, including family members and providers of care.
Site Map
Accessibility
Contact
Log In
Partnered with and generously funded by the National Institute of Nursing Research (Grant UC4-NR012584)
National Institute of Nursing Research

Development of PCRC Core Measures and Core Data Elements Library

- The PCRC has a standardized format for commonly used forms such as enrollment, demographics, and baseline clinical data.
- It is less costly for a study team and for the PCRC to pull from the common forms library; this also ensures uniformity in data collection. As new forms are developed for specific projects, then these will be reinvested into the common library.
- Also in development: a library of common data elements (e.g., Edmonton Symptom Assessment Scale is our preferred basic symptom inventory instrument)

Development of PCRC Core Measures and Core Data Elements Library (Cont.)

- When a common measure or data element is already in existence, it is more cost effective for the study investigator to use that element, as the informatics work and common data element programming is already done for those variables.
- Our forms and data elements are being transferred into a common data format and web-based data forms.
- The library will include 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.

Communication: A variety of modalities

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

PCRC PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

Issue 5, January 2014

Protocol #	Title	Study Phase	Site Status
PCRC 10-01	Statin Discontinuation	Manuscript Preparation	381; enrollment complete
PCRC 11-01	Pharmacovigilance	Phase I Rollout	9 (N=30)
PCRC 13-01	Best Supportive Care	Protocol Development	4 Sites TBA

New NINR R01 announced for PCRC-based studies
The PCRC is excited to share with you that NINR released a recent RFA to enhance the research and resource activities of PCRC by funding up to six high quality, cutting edge palliative care and end of life (PCEOL) research awards. **NOTICE**: Applications are now due **March 20, 2014** with the earliest start date September 1, 2014. We hope many of you will consider submitting a proposal! **Questions**? Contact carey.candrian@ucdenver.edu. Link to RFA http://grants.nih.gov/grants/guide/rfa-files/RFA-NR-14-003.html

PCRC Membership Committee
The first membership meeting to review new individual membership applications was held in December 2013. Be ready to welcome new members and sites to the PCRC community! Want to become a member? Complete the on-line application under "join us" on the PCRC home page. Questions about membership? Contact Membership Chair, Dr. Janet Bull or Jordan Lodato at pcrc@duke.edu.

REQUEST: PCRC Site Characteristics
All existing PCRC Members: if you have not already done so, please complete the on-line membership application. This will be an efficient way for the PCRC to provide a rich overview of what each site has to offer that we, in turn, can use as an ongoing resource for future studies and investigators. Thank you for your help!

Next Scientific Review Committee Meeting
If you are an interested investigator and have a research idea that would potentially align well with the goals of the PCRC, PCRC infrastructure and member sites, submit a Study Concept Form to the Scientific Review Committee (SRC). Forms are available on the PCRC website under the "studies" tab, and are due 10 days prior to the next scheduled SRC meeting: March 17, 2014.

How does my site become a study site?
All sites are eligible to be selected as a study site. In general, site selection is determined by the Study PI who identifies which site characteristics best align with their study design and objectives. For more information, check with the PCRC Operations team at pcrc@duke.edu.

UPDATE: Statin Trial Manuscript
The Statin Trial general main results manuscript is in final development! Stay tuned!

UPDATE: CRC Learning Community
The Clinical Research Coordinator (CRC) face-to-face meeting in Chicago last September was a huge success. We're culminating all of the feedback into our next action plans, site training and site support processes. Thanks for all that you do!

Spring Investigator Meeting in Chicago
We hope current members can join us Monday April 21 & Tuesday April 22, 2014 in Chicago, IL at a location convenient to the O'Hare (ORD) airport. We anticipate starting the meeting around 2:00pm CST on Monday and finishing about 3:00pm CST on Tuesday.

New Studies for You
PCRC 11-02: PCRC pharmacovigilance, a prospective observational study, is currently collecting data at 3 PCRC sites (n=30) to understand the clinical benefit and burden of adverse drug reactions and their impact on symptoms in the palliative care setting. The first medication being reviewed is gabapentin for neuropathic pain. The second medication to be reviewed is dexamethasone for anorexia. Sites for Phase II TBA.

PCRC 13-01: PCRC Best Supportive Care (BSC), a pilot study, seeks to test the feasibility of thorough documentation of BSC. Using a physician behavior intervention, this study will assess provider satisfaction with BSC at 4 PCRC sites this spring.

PCRC is partnered with and generously funded by the National Institute of Nursing Research (Grant 1U24NR014637-01)

Meetings

- Investigator In-Person**:
  - Semi-annual (1-2 day meeting, central location)
  - Spring & Fall
- Investigator Teleconferences
  - Every other month [2nd Mon, 11-12 a EST]
- Site Clinical Research Coordinator (CRC) Teleconferences
  - Every month [3rd Wed, 4-5 p EST]
- Study/ Project-Specific Teleconferences
  - Schedule per study, involved sites

** Described in more detail in Chapter 6

PCRC Site Visits

Overview

- Designed to highlight the strength of each organization, group & community
- Goal: better understand and support site practices and processes in light of their unique goals, as well as those of the PCRC

Methodology and Analysis

Participant observation (natural setting); conversational interviewing; document review; field note writing; grounded theory, coding; emergent themes and iterative discussion with sites post visit

Site Themes

Organization Structure, Culture, Best Practices/Things that add value, Relationships/Engagement, Creativity

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Chapter 6: RESEARCH

Guidelines for Interested Investigators

- If you have a research idea or activity that would potentially align well with the goals of the PCRC and benefit from PCRC infrastructure and member sites, we encourage you to submit a **Letter of Intent (LOI)** to the PCRC Scientific Review Committee (SRC).
- The LOI template is available online under the Studies tab, or by contacting the PCRC protocol specialist (carey.candrian@ucdenver.edu).
- The purpose of the PCRC LOI:
  - To help the SRC understand your research idea.
  - To provide relevant details for the SRC to determine whether the study goals of the proposed project align with the goals/priorities of the PCRC and would benefit from PCRC infrastructure and resources.
- The SRC will contact the investigator(s) within 10 days of LOI approval with an invitation to submit a full protocol, in collaboration with the PCRC.
- The SRC, chaired by Christine Ritchie, MD, MSPH, is a committee that reviews LOIs for new PCRC research and determines their potential impact on palliative care clinical practice and its evidence base, feasibility, and appropriateness for conduct through the PCRC.

New PCRC Study Development

There are 8 steps involved in developing, approving and rolling out a new PCRC protocol:

- Step 1: Letter of Intent (LOI)
  - Submitted first to Scientific Review Committee and then Steering Committee for final approval
- Step 2: Protocol Planning and Development
  - Protocol start-up meeting and timeline in line w/ PCRC performance metrics
- Step 3: Development of Data Dictionary/Analysis Plan
  - Step 2 and 3 happen concurrently
- Step 4: Scientific/Steering Committee Review
  - Efficient, transparent approach to review and approval re feasibility & appropriateness
- Step 5: Data Collection Tool (DCT)/Case Report Form (CRF) Content Meeting
  - Core Data Elements/Measures will inform study endpoint & measurement selection
- Step 6: Protocol and DCT/CRF Review (internal)
  - Final review for overall alignment and operationalization
- Step 7: 'Reconciliation' meeting
  - Changes addressed and incorporated as necessary
- Step 8: Study Rollout
  - Final receipt of protocol & related documents; rollout training meeting; official rollout

** also available on PCRC website

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

- Once protocols are approved by the SRC and Steering Committee, the PCRC will match site capabilities and potentially available study populations with the needs of the study.
- The PCRC currently has 47 different sites included in the network, 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.
- The next two slides show how to access LOI and protocol development information on our website.

Active Clinical Studies
Guidelines for Interested Investigators
- Protocol development and Study Rollout
- Protocol Instructions
- Protocol Template

Log In

Login Name

Password

log in

Forgot your password?

Guidelines for Interested Investigators

Information and documents to support the process for interested investigators.

Protocol development and Study Rollout

Read More...

Protocol Instructions

Read More...

Protocol Template

Read More...

Send this Print this

News

New protocol in development
Sep 18, 2013

Partnered with and generously funded by the National Institute of Nursing Research (Grant UC4-NR012584)

NATIONAL INSTITUTE OF NURSING RESEARCH

Active Clinical Studies

Guidelines for Interested Investigators

- Protocol development and Study Rollout
- Protocol Instructions
- Protocol Template

Protocol Development and Study Rollout

Download the document for specific details around developing a protocol for the PCRC and the study process.

Address specific questions to:

Send this Print this

News

New protocol in development

Sep 18, 2013

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Password

log in

Forgot your password?

Site Map Accessibility Contact Log In

Partnered with and generously funded by the National Institute of Nursing Research (Grant UC4-NR012584)

NATIONAL INSTITUTE OF NURSING RESEARCH

Authorship Protocol

- Full document available on PCRC website
- Each Study "Kick Off" 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, and
  - Final approval of the version of the manuscript to be published.
- Participation solely in the following does NOT justify authorship
  - acquisition of funding,
  - general supervision of the research group,
  - or the 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 Sustainability

Study Title	Type	Status	Funding
Statin Discontinuation	RCT	Enrollment complete manuscript prep.	NINR
Pharmacovigilance	Quality	Active enrollment - initial sites	CLHC & UC GIM*
Best Supportive Care	Implementation	Protocol Development	ACS
QDACT-PCRC	Quality	Protocol Development	AHRQ

* Duke University's Center for Learning Health Care and University of Colorado's Division of General Internal Medicine.

- Fall 2014 – 4-6 NINR-funded R01 studies to collaborate with PCRC
- Active discussions with Industry

PCRC Sustainability

- The PCRC is poised to grow exponentially due to the influx of additional U24 NINR funding as well as the NINR's RFA that will fund up to six new R01s run through the PCRC beginning in September 2014.
- Other funding sources such as PCORI, foundations, and industry are actively being pursued.

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Chapter 7: MEMBER OPPORTUNITIES

Privileges and Opportunities **

- Participate in voting as a member of your affiliated institution.
- Consider serving as a Study and/or 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. If you are unable to attend, you have the option of participating via teleconference.

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 investigator meetings
- Identify ways to collaborate with others
- Bring study ideas and study concepts forward to the PCRC SRC for consideration and review

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APPENDIX

Questions? Contact names and numbers

WHO TO CONTACT - PCRC OPERATIONS			
AREA	***WHO***	***PHONE***	***EMAIL***
Group Leadership/Grants/Membership/ Committees	**Amy Abernethy**	919-668-0647	*amy.abernethy@duke.edu*
Group Leadership/Grants/ Membership/ 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*
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/ Site Development	**Carey Candrian**	303-724-7892	*carey.candrian@ucdenver.edu*
Data Management/Statistical Analyses Policies	**Diane Fairclough**	303-724-1168	*diane.fairclough@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*
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