CRRO Clinical Research Resources Office

BU Clinical & Translational Science Institute

Supporting Clinical Research Excellence:

Launching the BMC/BU Medical Campus Research Professionals Network (RPN)

Mary-Tara Roth and Karla Damus
Clinical Research Resources Office
Office of Human Research Affairs
BU Clinical and Translational Science Institute (CTSI)

December 14, 2016

First…. A few updates

Trial Registration/Results Reporting: Clinicaltrials.gov

- HHS Final Rule (Sept 15, 2016)
  - Applicable clinical trials of FDA-regulated products: interventional trials (drugs, biologics, devices), Phase 2-4
  - Register within 21 days of enrollment of first subject; update at least every 12 months, & results reporting within 12 months of primary completion date
  - Rule effective date: Jan. 18, 2017
- NIH Policy (Sept 15, 2016)
  - All clinical trials funded wholly or partially by NIH, including phase 1 trials and trials that do not involve any FDA regulated products.
  - Register within 21 days of enrollment of first subject; update at least every 12 months, & results reporting within 12 months of primary completion date
  - Policy effective date: Jan. 18, 2017
- International Committee of Medical Journal Editors (ICJME)
  - Any human research project that prospectively assigns human subjects to intervention or comparison groups to study the cause and effect relationship between a medical intervention and a health outcome.
  - Register before first subject enrolled
  - No results reporting requirement
- BMC/BU Med Campus Policy
  - Any study that meets the definition of clinical trial must register with clinicaltrials.gov before IRB approval.
  - PI provides NCT number to IRB as documentation that the trial has been registered by the responsible party.

GCP Training

- New NIH Policy (Sept 16, 2017)
  - All NIH-funded investigators and staff involved in the conduct, oversight, management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6.
  - Effective Jan 1, 2017.

- BMC and BU Medical Campus Policy
  - Requires GCP training for clinical trial personnel submitting new applications to the IRB on or after Nov 1, 2016.
  - GCP training can be obtained by attending a CRRO in-person training (Fundamentals or PI training) or CITI GCP Course, or other applicable course such as NIH NIAID GCP Training.
    - https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx
  - GCP training will need to be renewed every three years.

  - *Coming soon:* Policy to include required GCP training for on-going NIH funded clinical trials submitted to the IRB prior to Nov. 1, 2016.
  - *Coming soon* for Social and Behavioral researchers: Social and Behavioral focused GCP training! Compliance expected by April, 2017.

Objectives

- Describe a clinical research coordinators (CRC)/research professionals network (RPN)
- Understand why these networks favorably impact the quality of research, the research process, and competencies of the research workforce
- Discuss the development, implementation, and how to get involved with the BMC/BU Medical Campus RPN

Well

MIND

How Meditation Changes the Brain and Body

By GRETCHEN REYNOLDS FEBRUARY 18, 2016 5:45 AM 296

Why Do So Many Studies Fail to Replicate?

Gray Matter

By JAY VAN BAVEL MAY 27, 2016

The New York Times

Health

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION ART

Study of Breast Biopsies Finds Surgery Used Too Extensively

By DENISE GRADY

Published: February 18, 2011

Too many women with abnormal mammograms or other breast problems are undergoing surgical biopsies when they should be having needle biopsies, which are safer, less invasive and cheaper, new research shows.

RESEARCH

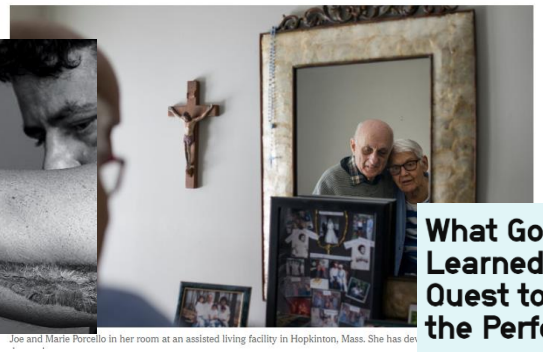
New Research Raises More Questions about Antidepressant Use During Pregnancy

By RACHEL RABKIN PEACHMAN DECEMBER 14, 2015 12:09 PM

HEALTH

Education May Cut Dementia Risk, Study Finds

By PAM BELLUCK FEB. 10, 2016



Joe and Marie Porcello in her room at an assisted living facility in Hopkinton, Mass. She has dev

HEALTH

Scientists Move Closer to Understanding Schizophrenia's Cause

By BENEDICT CAREY JAN. 27, 2016

What if PTSD Is More Physical Than Psychological?

A new study supports what a small group of military researchers has suspected for decades: that modern warfare destroys the brain.

By ROBERT F. WORTH JUNE 16, 2016

What Google Learned From Its Quest to Build the Perfect Team

New research reveals surprising truths about why some work groups thrive and others falter.

By CHARLES DUHIGG Illustrations by JAMES GRAHAM

FEB. 25, 2016

Heart Attack Risk Seen in Drug for Diabetes

JAN 13, 2015 @ 12:03 PM 60,547 VIEWS

Is Sitting The New Smoking?

David Sturt and Todd Nordstrom

CONTRIBUTOR

We write about how people and leaders achieve extraordinary results.

FULL BIO >

Opinions expressed by Forbes Contributors are their own.

TWEET THIS

Sitting is the most underrated health-threat of modern time.

research shows inactivity now kills more people than smoking

A study released by the American College of Occupational and Environmental Medicine suggests that, because you're human, you lose 11% to 14% of your productivity-potential every day. You check the news. You chitchat with a colleague in the next cubicle. You daydream about dinner, who is going to be on Jimmy Kimmel tonight, or your upcoming weekend road-trip. We're all human. We're not machines. And there's not much we do to change it.

Here's something you c

every health risk you p

N.F.L.'s Flawed Concussion Research and Ties to Tobacco Industry

By ALAN SCHWARZ, WALT BOGDANICH and JACQUELINE WILLIAMS MARCH 24, 2016

755

PHYS ED

The Close Ties Between Exercise and Beer

By GRETCHEN REYNOLDS DECEMBER 2, 2015 5:45 AM 130

BODY | FEBRUARY 11, 2013, 4:39 PM | 5 Comments

Stroke Procedure Challenged

By NICHOLAS BAKALAR

FACEBOOK TWITTER GOOGLE+ SAVE

4567

The usual treatment for ischemic stroke is an intravenous drug that dissolves blood clots, administered within four and a half hours of the first symptoms. In some cases, doctors also thread a wire through an artery in the groin to remove the clot in the brain mechanically and deliver drugs at the site of the clot.

THE WALL STREET JOURNAL.

LIFE | HEALTH | HEALTH JOURNAL

The Effects of Chronic Heavy Drinking on Brain Function Are Underdiagnosed

Alcohol-related cognitive decline may include impaired memory, decision-making and regulation of emotions and anxiety

The New York Times

HEALTH & WELLNESS

A Pill to Cure Addiction?

New medicines are being tested to help people quit

Recent [mildly paraphrased] quote from an FDA scientist

“At the end of the day, all this stuff winds up being data…. Someone is going to look at all of the data, drop-out rates, compliance, etc. and determine: where is it hanging together and where is it not? Someone is going to deconstruct that sausage. If you’re part of the chain of where this gets screwed up you’re part of a $100 million dollar effort that is screwed up…. If that data can’t be used.”

The clinical research enterprise….

- So, when we do research we are part of the “chain” effort that is done to generate new knowledge.
- New treatments/preventions, new practices, new standards, new processes….
- Great impact on lives of patients and public health
  - Strong links [in the chain] → positive impact

The research coordinator role

- AKA Research Assistant, Project Manager, Research Associate, Data Manager, Study Coordinator, Research Manager, Clinical Research Coordinator, *many more…*
- Works at a research site
- Under direction of Principal Investigator
- Responsible for conducting the study per institutional policy and per applicable federal regulations and guidelines

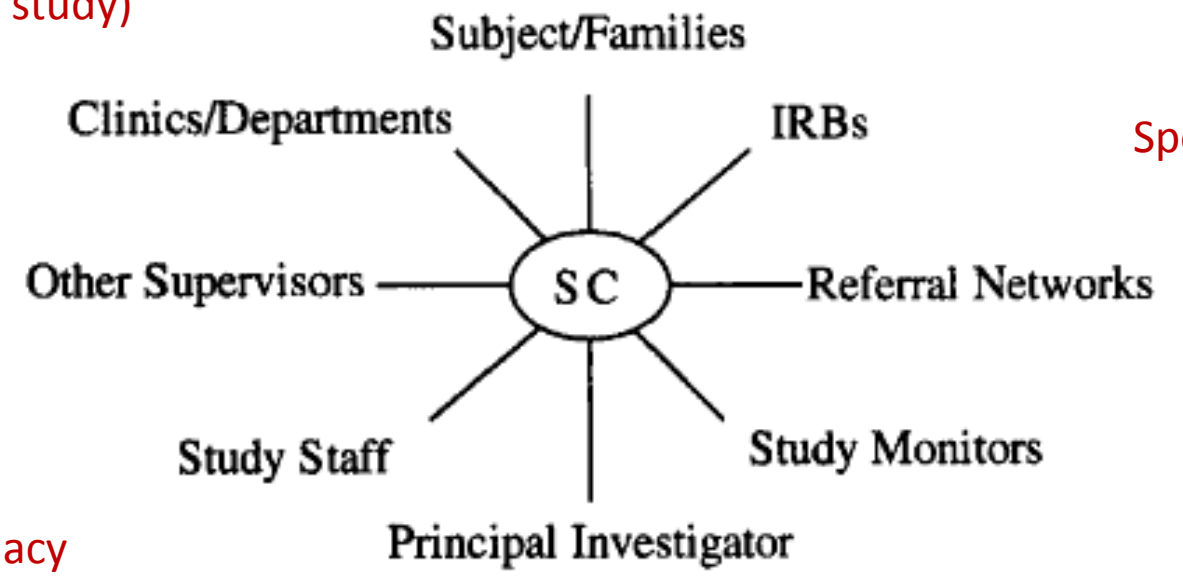
Essential role of the research coordinator

- “Glue that holds studies together…” (Duane and Munz, Monitor, 9/07)
- Important role in human subjects protection and ethical conduct of research
- Oftentimes the main contact with study participants
- Role in ensuring proper study conduct
  - Ultimately leading to quality of the research data
  - And ability of the data to answer the study question

Coordinator Rolesssssssssssssss

- Informed consent (participation in process)
- Budget preparation
- AE documentation/reporting
- IRB submissions
- Recruitment and screening of subjects
- Enrollment and Retention
- Recruitment strategy development
- Drug/device accountability
- Data Entry
- Coordination of team meetings and meetings with other sites
- Conducting/managing study visits
- Contract/budget negotiation
- Case Report Form (CRF) Completion
- Study initiation and close-out
- Managing study/source docs/reg. files
- IND/IDE FDA submissions
- Sample collection and processing
- Coordination of study visits and f-up care
- Self-audits
- Training of staff
- Research procedures/Compliance to protocol
- Payment of subjects
- Clinical trial registration and results
- Billing resolution
- Interface with sponsor and others
- Setting up systems and SOPs
- Prepping for audits
- Scheduling subjects

The Central Position of the Study Coordinator



Other sites

Privacy Officer

Funding Agencies

Laboratories (clinical and study)

Office of Technology Dev't

Finance

Sponsors

Regulatory agencies

Grants offices

Institutional COI

Data coordinating center

Investigational Pharmacy

Trial registration

Recruitment partners

Other institutional approvals

Clinical Trial Office

Potential subjects

Davis et al, "Invisible Hand in Clinical Research…" J. Law, Medicine & Ethics, 30 (2002): 411-419

Some trends affecting work of coordinators…..

- Complexity of study designs
  - Analysis of protocol data ~10K protocols from 75 pharma companies: 28 protocols 1999-2002 and 29 from 2003 to 2006
    - Annual growth rate of procedural frequency was 8.7%
    - Work burden increased 10.5% per year; avg. length of a CRF increased 227% (55 to180 pgs) *Getz, RAJ Pharma, May 2008, 315-316*
- Increase in multicenter trials
- Some decreases in research funding (do more with less)
- Increased national attention (thru CTSIs, etc.) to bring new therapies to the public more quickly: "Turning scientific discoveries into health benefits takes too long…"

Study Coordinator trends in the job

- CRC workload increasing 6% a year…
  - Desire to enroll subjects faster
  - Increased study complexity
- CRC turnover rate increasing…
  - 56% CRCs in current position for <3yrs
  - Burnout due to heavy workload and low compensation
- # CRCs with experience decreasing…
- What are possible effects?
- What are possible solutions?

CG Duane et al, Study Coordinators' Perceptions of their Work Experiences, The Monitor, Sept. 2007

Challenges to a well-prepared and qualified workforce – from coordinator surveys

- Inadequate training
  - 45% reported receiving no training and 17 % reported they received on the job training without a mentor *
- Coordinator workload often greater than time allotted*
  - Multiple PIs, multiple studies**
  - Increasing workload: 7% a year 2002 – 2012***
- Few advancement opportunities *
- Little recognition *
- Inadequate pay (20%)**

*Duane and Munz, Monitor, Sept 2007, 39-42.
**Speicher, et al, Clin Transl Sci. 2012 Dec; 5(6): 470-475.
***Getz, Forte Research Newsletter, 1/29/13

AHC Clinical Research Challenges

- Pfizer data from 2006-2009 (presented at CTSA Clinical Trials Management Conference, 2009, B.W. Morrison)
  - 30% of activated sites don't enroll a single pt.
  - 50% don't enroll more than 3 pts
  - Final protocol received by site to first enrolled subject: median of 265 days
  - Final protocol to contract signed: median of 165 days

AHC Clinical Research Challenges

- Protocol Performance and Resource Utilization from 16 Cancer Centers (presented at CTSA Clinical Trials Management Conference, 6/10, H. Durivage, Yale Center for Clinical Investigation)
  - 170 Phase II Investigator-initiated trials at 16 cancer centers: 34% (58) not completed due to inadequate accrual.
  - 3320 pts enrolled; 684 (21%) enrolled to trials not completed due to inadequate accrual
  - Cost of non-accrual at the 2 median sites
    - 3K hrs/center/year or $180K per year per center!
    - 1.8M for all centers!

NCATS

National Center for Advancing Translational Sciences

ncats.nih.gov/ctsa

Clinical and Translational Science Awards Program

Catalyzing Innovation

Turning scientific discoveries into health benefits takes too long. To help get more treatments to more patients more quickly, the Clinical and Translational Science Awards (CTSA) Program supports an innovative national network of more than 50 medical research centers that work together to improve the translational research process.

Led by the National Institutes of Health's National Center for Advancing Translational Sciences, the CTSA Program is designed to tackle system-wide scientific and operational problems to make the clinical and translational research enterprise more efficient. CTSA Program research centers serve as hubs locally and regionally to catalyze innovation in training, research tools and processes.

CTSI and workforce development

- “Training investigators and research teams to competently conduct clinical research is crucial to successful translation of novel drugs, devices and interventions. Currently there is substantial variation in quality of design, execution, reporting and analysis of clinical trials.”
- 2 initiatives:
  - Determination on what is the basic level of training required for researchers.
  - Identifying/developing competency-based training for further development of investigators and clinical research professionals

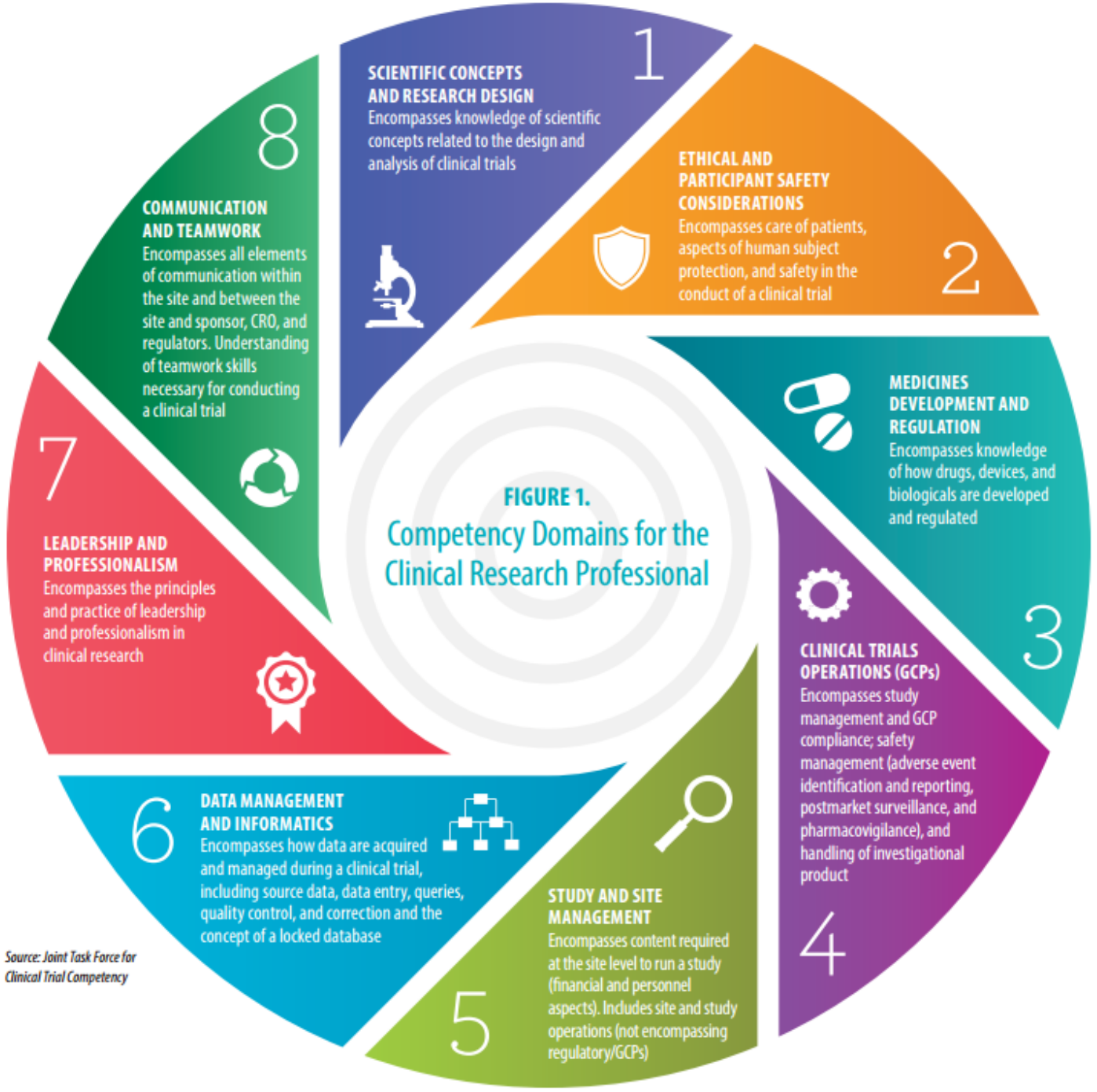
CTSA Supplement Award 2014

ECRPTQ (Enhancing Professionals' Training and Qualifications)

Based on recommendations from the Joint Task Force for Clinical Trial Competency (part of Multi-regional Clinical Trial (MRCT) Center at Harvard)

1) Scientific concepts and research design
2) Ethical and participant safety considerations
3) Medicines development and regulation
4) Clinical trials operations (GCPs)
5) Study and site management
6) Data management and informatics
7) Leadership and professionalism
8) Communication and teamwork

Sonstein et al, Moving from Compliance to Competency…., Clinical Researcher, June 2014, 17-23.



BU CTSI and Workforce Development

- The Coordinator network underscores the recognition by the institution of the importance of the coordinator role and of providing support to the individuals in this role who play an integral role in the safe, ethical, and efficient conduct of research.

- The goal of this network will be to provide a professional forum for research coordinators to network and exchange ideas and develop within the profession.

[CTSA] Research Coordinator Taskforce

- **Mission -**To support the professional development of Clinical Research Coordinators (CRCs) and help guide institutions how to organize and network their CRC workforce.
  - In 2014 CTSA Steering committee ended the committee structure; the RC Taskforce continues outside of CTSA support to share ideas and common efforts.
- *Initiatives:*
  - Develop standardized job descriptions to promote career paths
  - Develop approaches to support the retention of CRCs
  - Develop recommendations for education & training
  - Promote the formal certification of CRCs
  - Develop models for Academic Health Centers to organize and network their CRC workforce

Coordinator Networks

- 1st CTSI-supported Networks ~ 2006 (U. Iowa)
- Characteristics
  - Formal governance (advisory board, leadership group, etc.)
  - Formal mission statement
  - Formal meetings
  - Institutional support

- Services
  - Networking
  - Education/training specific to coordinator role
  - Mentoring
  - Sharing of experiences, knowledge, resources
    - Not having to keep recreating the wheel
    - Concentrate efforts on solving new challenges
  - Professional recognition

RPN Development at BMC/BUMC

- Key informant interviews
  - N=5, Jun and Jul 2016
- Review of other CTSI CRC/RPN websites
  - N=18, Aug 2016
- 2 Focus Groups at the CTSI
  - N=10, Sep and Oct 2016
- Development of RPN website with link to join the RPN
  - Launched Dec 2016
- CRRO staff leadership, Jan 2017

Key informant interviews

- Susan Rose- USC (phone interview)
- Nancy Needler- U Rochester (phone interview)
- Michelle Jenkerson- WUSTL (phone interview)
- Bob Kolb- UFL (phone interview)
- Lisa Tucker- BUSM, Peds ID (in person interview)

Key informant interview questions

1. How long have you had a CCN/RCN?
2. How was it established? And by whom?
3. What is the overall stated goal or purpose of the network?
4. What is the structure and who is responsible for the various resources (eg website, newsletter, directory, job ladder, educational venues, etc)?
5. How is it funded? How much time does it take to support/maintain it?
6. How do new research coordinators find out about the CCN? How many members /coordinators are in your network?
7. Is there mandatory/voluntary training/educational venues? How many venues do you offer? How is the training organized (by experience? job title? need?)
8. Do you encourage/support certifications? Which certifications do you think are the best to obtain? Does the CCN assist with obtaining certifications or for maintenance requirements for certification?
9. To you have any programs to recognize the coordinators?
10. Do you have working groups for specific activities?
11. What kind of ongoing meetings do you have? What frequency? How many attend? What topics?

12. Do you have an annual meeting? What is involved? Do you prepare an annual report? If yes, can I review the report?
13. What are some of the lessons learned in establishing the network, maintaining it and expanding it? What works well/does not work well?
14. Is there a regular survey of your CCN members? If yes, please describe details- frequency, content, response rate, etc.)
15. Is your directory of CCN members online? Do members update their information? Is it used to fill/advertise positions?
16. Do you have specific job descriptions for various research related roles? Is there a career ladder?
17. Have you encountered barriers to the network? How have you overcome them?
18. What are the aspects that have contributed (the most/the least) to the success of your network?
19. How big a support is the leadership in your institution of the network?
20. What is your vision for your CCN moving forward?
21. What advice would you give us as we set up our network?
22. Are there key resources/meetings that will be helpful to us?
23. Other comments?

Major themes from key informant interviews

- Leadership buy-in is essential
- Everyone is busy
- Foster community among coordinators
- Create a governance structure
- Develop a web site for coordinators/the network
- Create a communication exchange
- Establish mechanisms to share resources/tools
- Develop effective ways to share ’lessons learned’

Major Themes from Key Informant Interviews (cont)

- Set up an effective mentoring system
- Provide educational venues
- Have an annual coordinators meeting with food
- Establish a recognition/awards program
- Advertise educational opportunities
- Support certification from ACRP, SOCRA, etc if possible
- Work with HR to create job titles/descriptions for promotion/advancement
- Create a job bank for coordinators and to assist investigators
- Develop programs to promote wellness

News

Tweet | Recommend 1 | G+1 0

CTSI Establishes Network of Clinical Research Professionals to Support Critical Workforce

9.10.2013

Working tirelessly behind the scenes of breakthrough clinical research at the University of Miami are teams of professionals who play a vital role in advancing quality research that improves the lives of patients. These support staffers include research nurses, coordinators and others of varying backgrounds and expertise who interact with study participants, gather data and navigate regulatory processes.

Recognizing this workforce as a critical component to clinical investigations at UM, the Miami Clinical and Translational Science Institute (CTSI) has created the Network of Clinical Research Professionals (NCRP), an organization dedicated to developing education, training, career development, and networking opportunities for research support staff. The group's next meeting is scheduled for September 17.

"As an institution, we need to acknowledge the critical efforts of the people who do research work—the clinical coordinators, research nurses, regulatory staff, data managers, and others who make research possible," said John Bixby, Ph.D., Vice Provost for Research and executive committee member of the Miami CTSI. "NCRP seminars are designed to allow those closest to the research process to articulate challenges and suggest solutions—to build a foundation for clinical research based on best practices across the University."

One of the major goals of the Miami CTSI, which received a $20 million grant from the National Institutes of Health last year, is to promote excellence in clinical research training. "We want to have a strong workforce that is well trained and prepared to do high-quality research and who feel like they are valued," said JoNell Potter, Ph.D., co-director of ¡Alianza! Miami Center for Research Participation and Partnership, the Miami CTSI program working on developing training modules, mentoring opportunities and a career ladder for coordinators and research support staff.

With support from the Miami CTSI, the NCRP held its first seminar in May, when more than 100 people came out and provided valuable feedback on the needs of clinical research staff. A group survey of these key staffers found that their job titles varied widely, from administrative assistant to research associate, and that many were self-taught or learned their skills on the job.

"What they told us over and over again was that they wanted opportunities to learn more skills and grow professionally."

Barbara Lutz, RN, research assistant in Rehabilitation Medicine, shows Robert Berelos strengthening exercises at the Clinical Research Center for UM's Shoulder Pain and Chronic Spinal Cord Injury Study.

Related Departments

Clinical Research Center (CRC)

Miami Clinical and Transitional Science Institute (CTSI)

Related Articles

FDA Commissioner Headlines Clinical Trials Symposium, September 14-15

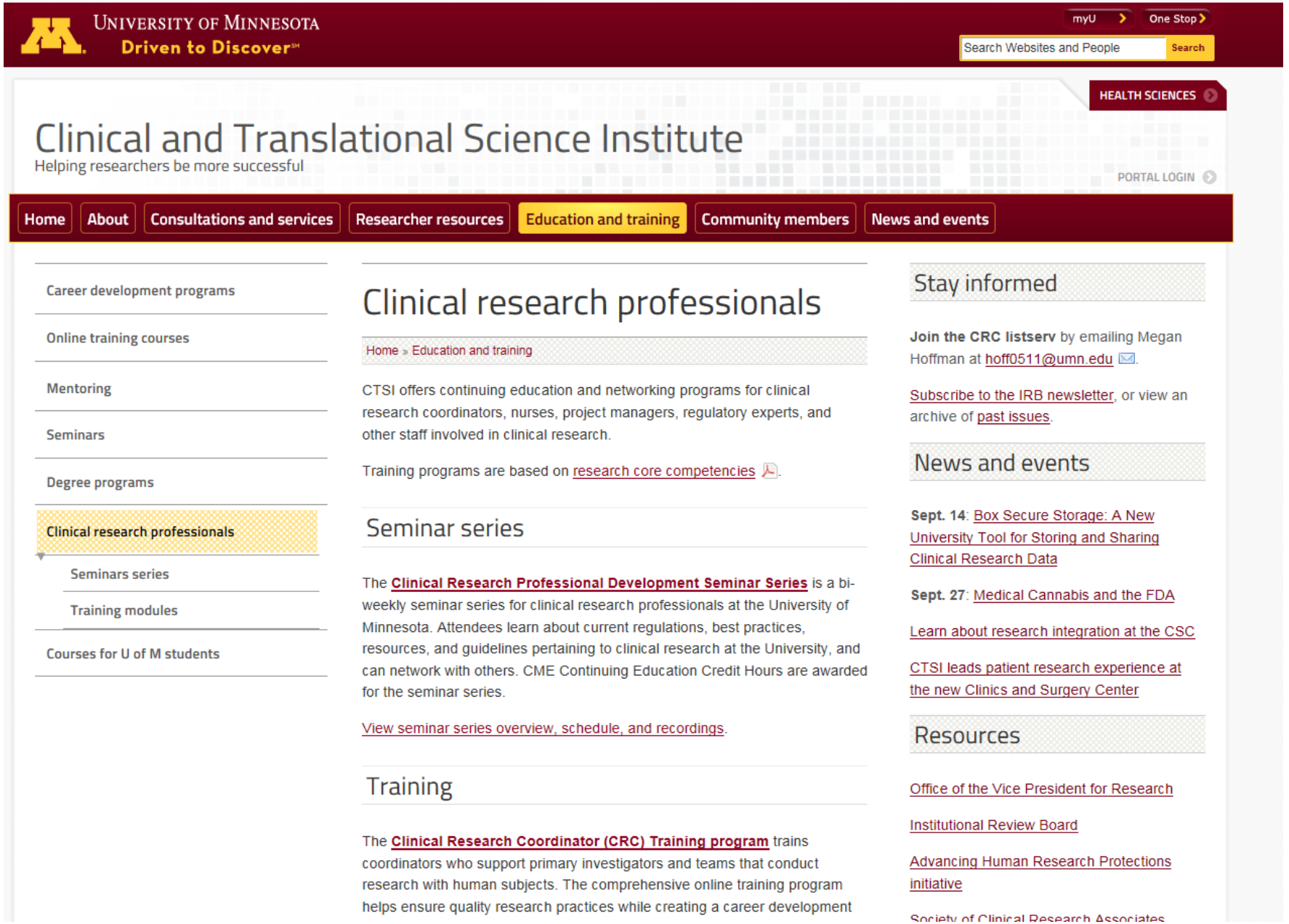
Innovative Community-Based Health Screening Initiative Prepared for Launch

Otolaryngology Researchers Develop New Approach to Improve Efficacy of Cochlear Implantation

Women in Academic Medicine Symposium Focuses on Creating Leadership Skills and Career Advancement

http://med.miami.edu/news/ctsi-establishes-network-of-clinical-research-professionals-to-recognize-an

www.ctsi.ufl.edu/education/research-coordinators/



www.ctsi.umn.edu/education-and-training/clinical-research-professionals

NRP
Network for Research Professionals

UNC
THE NORTH CAROLINA TRANSLATIONAL & CLINICAL SCIENCES INSTITUTE

Home | About Us | Education | Mentoring | Best Practices | Research in Epic

The UNC-NRP is a peer group that is open to all research personnel on campus to help increase awareness and communication of best practices through a series of educational seminars, resources, mentoring and networking programs.

We are excited to have this forum to facilitate campus-wide improvements in the overall management of clinical, social, and translational research.

To join the UNC-NRP, email us using the button below.

Join Us

Keep in touch with your peers! Join the unc.crc listserv

Orientation for New Clinical Research Personnel Series

The next series will be held for five Wednesdays beginning March 8, 2017 from 1:30 - 4:00pm in room 219, Brinkhous-Bullitt Bldg.

https://nrp.tracs.unc.edu/

NCRP MENTORING SUBCOMMITTEE
Request To Be A Mentor Form

Name: _____ Today's Date: _____

Department: _____ Email Address: _____

Phone: _____ New to clinical research? Y / N *If no*, years of experience: _____

Please describe your area of expertise / specialist area_____ _____

_____

Which research areas do you wish to offer mentoring in ? (*Please check all that apply*):

- ❑ IRB Submission – New Study
- ❑ IRB Submission – Post Approval
- ❑ Other Regulatory Documents
- ❑ Study Design
- ❑ Advertisement
- ❑ Consent Forms or Process
- ❑ Regulatory Binder
- ❑ Participant Binders (Source Documents)
- ❑ Participant Recruitment
- ❑ Participant Retention
- ❑ Participant Compliance
- ❑ Regulatory Compliance
- ❑ Case Report Forms
- ❑ Radiation Safety
- ❑ Working with OCT
- ❑ CTRC Issues
- ❑ Human Research Ethics Training
- ❑ New Coordinator Training
- ❑ Data Safety Monitoring
- ❑ Good Clinical Practice Guidelines
- ❑ Adverse Events
- ❑ Participant Compensation
- ❑ ClinicalTrials.gov
- ❑ 98 Account/Billing Issues
- ❑ WebCIS
- ❑ Information Security
- ❑ Interim or Final Reports
- ❑ Grant Applications
- ❑ Other (Please specify): _____

When do you want to start with your mentoring role? _____

How much time can you allocate?_____

Circle mentoring preference

- face to face
- Phone
- email

Thank you for submitting this request. Someone will contact you soon to connect you with a mentor.

Version: 5/21/2012

SC CTSI Home Research Services and Tools News About Us

ABOUT HOME ABOUT SC CTSI CORE GROUPS LEADERSHIP OUR PARTNERS NEWS JOB OPPORTUNITIES

Search

Join our team as the Protocol Coordinator - Research Nurse (RN)! ***Full-Time and Part-Time Opportunities Available***

Join our team as the **Protocol Coordinator - Research Nurse (RN)**!

The Southern California Clinical and Translational Science Institute (SC CTSI) is a research organization at the University of Southern California (USC) and Children's' Hospital Los Angeles (CHLA). Our mission is to support, promote and accelerate scientific discoveries and their application in real-life settings to improve health in diverse populations. SC CTSI develops and provides resources, services, trainings and tools in support of researchers, academic leadership and partners that collaborate to achieve this exciting mission.

The Protocol Coordinator(RN) will join a team dedicated to supporting clinical researchers across USC schools. Assists investigators and their research teams in conducting clinical research while adhering to good clinical practices, patient care standards as well as institutional policies and procedures. Provides a range of study-related services at the highest professional level of nursing standards. Supports all phases of research studies ranging from participant recruitment, assessment, treatment, data collection, and follow-up for enrolled patients. Provides input to principal investigators, staff nurses and patients that effects clinical research studies from the initial protocol design to completion of study. Participates in problem solving to provide solutions to any operational impediments and develop new strategies to improve execution of research. Provides technical support and guidance to other nurses and coordinators in the care of patients. This role will have the opportunity to work on studies of varying disease types.

Key Responsibilities:

• Assists principal investigator in coordinating all phases of research studies including recruitment, assessment, treatment, data collection and follow-up for enrolled patients. Plans, organizes and schedules activities to meet research study objectives. Critiques in-house research studies prior to implementation. Provides input to principal investigators regarding the protocol design and analysis. Implements multiple research studies, as needed. Participates in recruitment of patients, data collection and follow-up for patients enrolled in a research study.

www.sc-ctsi.org/

December 12, 2016 | IRB and Human Subjects Research Updates

Office for the Protection of Research Subjects

USC

Research Coordinator Bulletin

New Quick Guide for Study Start Up

The essential links and regulatory documents needed to conduct a clinical trial reside on a number of USC websites. OPRS has launched a new page in order to make the necessary information available in one place. Contributions to this effort have been made by research coordinators and staff, and we invite your input with regard to updates and process changes as they are issued. Link to: Study Start-Up

SAVE THE DATE! Research Coordinator Education Luncheon

January 26, 2017
Norris Topping Tower 7409, 12 Noon

BMC-BUMC focus group objectives

- Discuss participants' ideas, suggestions, vision, experience, recommendations on selected topics related to a research professionals network at BMC/BUMC
- Identify additional topics and components that need to be addressed
- Describe potential resources
- List next steps
- Be respectful of participants' time

Selected topics for the focus groups

- “the Network”- what is it, what should it do, how should it be structured, governed, who are the members, working groups, services offered, activities, resources, website, training opportunities, mentoring, job descriptions and opportunities, its importance, etc
- Goals, vision and mission
- Name for the network
- Advisory council/board
- Member led working groups- on what topics
- Website, survey, annual meeting, recognition of members,

BMC/BUMC focus group key findings

- Mission and vision of the network needs to be focused and specific; make it concrete. What are we building a network to do?.
  - Our vision for the department is to expand research capacity, and to expand interdepartmental collaborations, so having a central network would help connect people from different departments
- The role of the coordinator or research assistant is different in different departments
  - In some the research coordinator is responsible for everything (protocol, subject recruitment, regulatory, all the IRB) or they have a central IRB person.
  - Also different departments have different needs; some need a network, some need to do IRB but some don't.
  - Different job titles mean who should be in the network should be oriented by responsibilities. Is your responsibility regulatory, recruitment, data analysis, where do you fall? The scope is important in this forum. Need to identify the overlaps.
- Constantly "reinventing the wheel" when it comes to information; a lot of people creating the same thing over and over. Multisite projects as well; different sites have different consent forms so we need to reinvent the wheel when dealing with other coordinators and sites.
- "Need to teach yourself: the PI isn't always right, but when you're just starting out you don't know what's correct and what's not and getting the correct information is not efficient."

BMC/BUMC focus group key findings

- “We end up in research silos, so it can be very hard to know who to reach out to. You want to be able to say I have this, do I need to completely reinvent the wheel for it?”
- “If I don’t have the language for something I would like to ask if someone has an SOP for this that I can just make edits and send to the PI. It would be great to have a bunch of well written SOPs templates that van be shared for use by others”
- “A centralized place to share documents and tools is essential. You should never start with a blank document.”
  - Need a study starter kit; if there is one being created by a research team how can it be shared?
- A place where you know that some things are written in stone, like NIH guidelines or Mass law, some stuff where it depends on your sponsor so you need to ask how they want it done, then it’s up to the supervisor for other things. Just so you know this is what you have to do, this is what it’s up to you, and this is the grey area.
- A lot of people don’t know about the CRRO and other CTSI resources; it would be helpful to have a manual that could be passed on to someone if they leave.

BMC/BUMC focus group key findings

- “Coming up with more institutional standards for trainings, just for base practice and competency. Maybe monthly, so when an RA comes on board they can be trained. These standards need to be the same for long term studies as well; since its minimal risk people think its fine, but then these practices get into other studies. There’s a study specific training manual, usually used by the RAs, but a general one for training expectations. A resource like this might exist somewhere else, but I don’t know about it so I’d write the exact same thing. If I leave they won’t use mine, they’ll just make yet another one.”
- “I always feel like I could know more, and for my group as well it feels like there’s a lot of disparity in knowledge of how to go about things. I know everyone can’t know everything, but if I get hit by a truck I don’t want the whole section to come to a standstill. “
- We need to change the concept held by many PIs that monitoring is bad, as if you’re trying to prove that something wrong was done, especially new employees who are afraid to say anything.

BMC/BUMC focus group key findings

- Often a lot of blame for doing things wrong
- How to deal with the “kitchen sink” of responsibilities and activities expected
- How to cut down the workload of teaching new interns
- Beyond just general information, sometimes it gets so specific depending on what department you’re in, or the research you’re doing. We should have both big general guidelines and rules but also the little tidbits on a more specific level.
- It would be wonderful if some part of this network had a part where you could meet other coordinators so you could start putting faces to names and saying, everyone here knows each other, don’t be afraid to reach out, because everyone here is there with the expectation someone might call on them.”
  - Start with an event only for research coordinators, mainly just meeting people and breaking the ice.
  - Then create rotating office hours with an email blast with who will be in the office, willing to answer questions. Like a rotating mentorship.
- For governance a leadership group is needed, different from the advisory board, meeting more times a year. Maybe the leaders of working groups could come together to be the voice of the whole working group.

BMC/BUMC focus group key findings

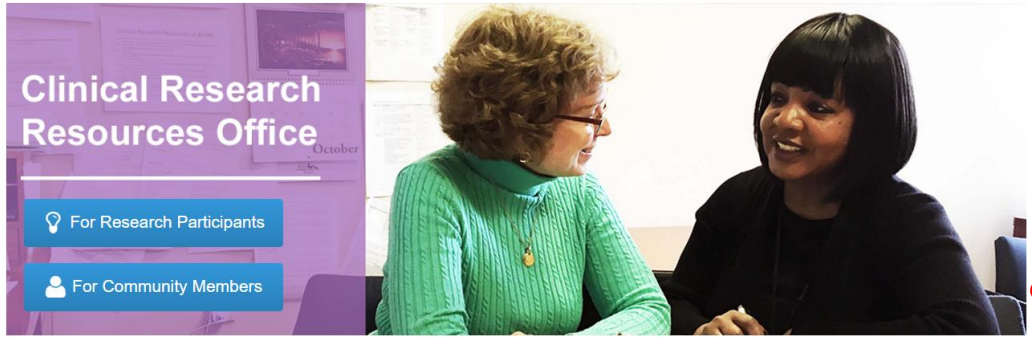
- Meetings
  - Lunchtime or around 1 is good if food is provided you don’t need to worry about getting it. Send out a blast email saying we’re going to hold an event where the goal is to meet people you may not have matched with, for an hour, so it doesn’t feel like too much.
  - Maybe something quarterly? After a CRRO seminar we could have dessert across the hall, for those who were interested or couldn’t attend the earlier meeting. People could sign up for working groups or other roles if they want to.
- Network directory
  - Create a directory where people have control over their information.
  - Could be like Craig's list, where you let people know you’re available so the PIs could look at it. Identify mentors or mentees on certain topics, based on needs and expertise. It’s important everyone can look at it. Shouldn’t be too formulaic.
- Periodic surveys of the network should be done

Launching the BMC/BUMC RPN

Major objectives of the RPN

- Improve the competency of BMC/BU Medical Campus research professionals through educational seminars, trainings, mentoring, resources and other networking programs
- Support an effective, efficient system to keep network members up to date on changing policies and regulations
- Increase awareness and communication of best practices and innovation to promote subject recruitment, retention and satisfaction
- Reduce barriers to translation of research findings
- Maximize satisfaction and productivity of all members of the research team
- Provide career development opportunities for network members

Boston University Medical Campus and Boston Medical Center:
Clinical Research Resources Office



Welcome! We're here to help you in your clinical and human research.

The mission of the Clinical Research Resources Office is to facilitate the design and conduct of ethical and scientifically valid clinical and human research by providing a range of services, resources and guidance to support BMC and BU Medical Campus clinical researchers in planning, submitting, conducting and analyzing their research. In fulfilling this mission, the CRRO strives to:

- **Facilitate research** by providing guidance and tools that are relevant, focused, accessible, and current.
- **Be responsive to needs** of the BMC and BU Medical Campus clinical research community, the needs of research participants, and the changes in regulations and policies guiding human research.
- **Centralize expertise and support** for the conduct of human research.
- **Support & enhance the research workforce** infrastructure to maximize quality of research.
- **Foster research participant advocacy** by promotion of best practices to ensure the safe and ethical conduct of human research.

The Clinical Research Resources Office receives major funding support from the Boston University Clinical & Translational Science Institute (CTSI). The BU-CTSI is an NIH center of expertise, providing tools, services and

About Us
- About the CRRO
- Meet the CRRO Team
- Contact Us

Consultations
Training & Education
Past seminars
Research Professionals
Resources
Request CRRO Services

Quick Links

BU CTSI
Clinical Data Warehouse
ClinicalTrials.gov
CR Times Newsletter
For Community
For Research Participants
HRPP Policies
INSPIR II
PI Responsibilities
Required Training

www.bumc.bu.edu/crro/

The BMC/BU Medical Campus Research Professionals Network (RPN)

An important initiative and service of the CRRO/CTSI is the recently launched Research Professional Network (RPN). Its overarching goal is to ultimately enhance the quality of human/clinical research at the BMC/BU Medical Campus through an effective network for research professionals. Some of the major objectives of the RPN are to:

- Improve the competency of BMC/BU Medical Campus research professionals through educational seminars, trainings, mentoring, resources and other networking programs
- Support an effective, efficient system to keep network members up to date on changing policies and regulations
- Increase awareness and communication of best practices and innovation to promote subject recruitment, retention and satisfaction
- Reduce barriers to translation of research findings
- Maximize satisfaction and productivity of all members of the research team
- Provide career development opportunities for network members

The RPN has an Advisory Board with representatives from the various research roles and from the major departments and offices at BMC/BUMC involved in the conduct, support and regulation of human/clinical research. There are many RPN projects which are designed, implemented and evaluated by working groups in collaboration with the OHRA, CRRO and CTSI staff. These working groups are led by network members and address specific needs or topics such as GCP, tools for research studies, recruitment/retention, informed consent issues, training, mentoring, communication venues, and more! There is an annual RPN meeting where members can interact and celebrate successes and an annual RPN member survey to provide a dynamic needs assessment and metrics to help plan and evaluate RPN activities.

About Us
Consultations
Training & Education
Past seminars
Research Professionals
Research Professionals Network
Join the Network!
Resources
Request CRRO Services

Quick Links

BU CTSI
Clinical Data Warehouse
ClinicalTrials.gov
CR Times Newsletter
For Community
For Research Participants
HRPP Policies
INSPIR II
PI Responsibilities

www.bumc.bu.edu/crro/research-professional-network/

The RPN has an Advisory Board with representatives from the various research roles and from the major departments and offices at BMC/BUMC involved in the conduct, support and regulation of human/clinical research. There are many RPN projects which are designed, implemented and evaluated by working groups in collaboration with the OHRA, CRRO and CTSI staff. These working groups are led by network members and address specific needs or topics such as GCP, tools for research studies, recruitment/retention, informed consent issues, training, mentoring, communication venues, and more! There is an annual RPN meeting where members can interact and celebrate successes and an annual RPN member survey to provide a dynamic needs assessment and metrics to help plan and evaluate RPN activities.

Membership in the RPN is open to all BMC/BUMC research personnel involved in clinical/human subjects research such as research managers, study/clinical/research coordinators, data managers/analysts, and research assistants.

If you are interested in becoming a member of the RPN please sign up here! You can also specify which working group/s you may want to join. If you have any questions please contact Karla Damus at damusk@bu.edu.

Join the Network!

The Clinical Research Resources Office receives major funding support from the Boston University Clinical & Translational Science Institute (CTSI). The BU-CTSI is an NIH center of expertise, providing tools, services and resources to clinical investigators, maximizing the impact of discoveries & speeding the translation of research into improved patient care. Please cite the BU-CTSI grant number in relevant publications (1UL1TR001430).

ClinicalTrials.gov
CR Times Newsletter
For Community
For Research Participants
HRPP Policies
INSPIR II
PI Responsibilities
Required Training

www.bumc.bu.edu/crro/research-professional-network/

Join the Network!

Please complete the form below to join the Research Professionals Network! We are happy to have you!

*= required information.

Name *

First | Last

Email *

Phone *

Employee of: *

- BU employee
- BMC employee
- Other

School/Med Center: *

- BUSM
- BU GSDM
- BUSPH
- BMC
- Other

About Us
Consultations
Training & Education
Past seminars
Research Professionals
Research Professionals Network
Join the Network!
Resources
Request CRRO Services

Quick Links

BU CTSI
Clinical Data Warehouse
ClinicalTrials.gov
CR Times Newsletter
For Community
For Research Participants
HRPP Policies
INSPIR II
PI Responsibilities

http://www.bumc.bu.edu/crro/research-professional-network/join-the-network/

Next steps

- Sign up for the RPN
- Indicate which working group/s you would like to join
- Complete an annual survey (beginning Jan 2017- baseline)
- Meet with your research teams and discuss how and in what ways the RPN can facilitate your research activities
- Communicate your ideas with the CRRO
- Check the RPN website regularly for updated information and announcements of RPN events (these will also be emailed to RPN members)
- Let’s make the BMC/BUMC RPN the best network in the CTSI!

CRRO Clinical Research Resources Office

BU Clinical & Translational Science Institute

Thank you!!

Please join the BMC/BUMC RPN

www.bumc.bu.edu/crro/research-professional-network/join-the-network