Supporting Clinical Research Excellence:

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

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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
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 Roles

- 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

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.
***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!
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 /coordinates 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
CTSI Establishes Network of Clinical Research Professionals to Support Critical Workforce

Working tirelessly behind the scenes of breakthrough clinical research at the University of Miami are literally thousands of professionals who play a vital role in advancing quality research that improves the lives of patients. These support staff 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 U-M, 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 Risty, Ph.D., Vice President 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 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 Jofeith Potter, Ph.D., co-director of the Miami CTSI.

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 staff members found that their job titles varied widely, from administrative assistant to research associates, and that many were 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 Berdos, strengthening exercises at the Clinical Research Center for U-M’s Shoulder Pain and Chronic Spinal Cord Injury Study.

Related Departments
- Clinical Research Center (CRC)
- Miami Clinical and Translational 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
Research Coordinators

The CTSI Translational Workforce Development Program offers the following opportunities for research coordinators:

CTSI Certificate of Basic Coordinator Training
Entry-level education for those who wish to become a clinical research coordinator, including health professionals working in nursing, nutrition, respiratory therapy, occupational/physical therapy, or similar allied health fields.

UF Research Coordinators Consortium
Forums for networking, education and resource sharing among UF research coordinators.

Research Coordinator Certification Study Groups
Facilitated study groups for clinical research professionals seeking national certification.

Research Coordinator Leadership Development Program
Six-month program with monthly two-hour sessions designed to develop the next generation of leaders in the field of research coordination.

Other CTSI Opportunities
Graduate Certificate in Biomedical Informatics
Clinical and Translational Science Institute
Helping researchers be more successful

Clinical research professionals

CTSI offers continuing education and networking programs for clinical research coordinators, nurses, project managers, regulatory experts, and other staff involved in clinical research.

Training programs are based on research core competencies.

Seminar series

The Clinical Research Professional Development Seminar Series is a bi-weekly seminar series for clinical research professionals at the University of Minnesota. Attendees learn about current regulations, best practices, resources, and guidelines pertaining to clinical research at the University, and can network with others. CME-Continuing Education Credit Hours are awarded for the seminar series.

View seminar series overview, schedule, and recordings.

Training

The Clinical Research Coordinator (CRC) Training program trains coordinators who support primary investigators and teams that conduct research with human subjects. The comprehensive online training program helps ensure quality research practices while creating a career development

Stay informed

Join the CRC listserv by emailing Megan Hoffman at ctsimail@umn.edu.

Subscribe to the IRB newsletter or view an archive of past issues.

News and events

Sept. 14: Box Secure Storage: A New University Tool for Storing and Sharing Clinical Research Data

Sept. 27: Medical Cannabis and the FDA

Learn about research integration at the CSC

CTSI leads patient research experience at the new Clinics and Surgery Center

Resources

Office of the Vice President for Research

Institutional Review Board

Advancing Human Research Protections initiative

Society of Clinical Research Associates
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.

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 - 4:00 pm in room 219, Brink house-Bullitt Bldg.

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

www.bumc.bu.edu/crro/research-professional-network/
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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).
Join the Network!

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

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• 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!
Thank you!!

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