

The BMC/BU Medical Campus Research Professionals Network:

Supporting Clinical Research Excellence

Updates and Future Plans

Objectives

- Discuss the history of coordinator networks and the importance of the coordinator role in workforce development.
- Describe the status of the BMC/BU Medical Campus Research Professionals Network.
- Describe the benefits of joining the Research Professionals Network.

NCATS CTSA

ncats.nih.gov/ctsa

About the CTSA Program



Learn more about the CTSA Program and clinical and translational research across the country.

- CTSA Program Hubs
- Collaborative Innovation Awards
- Trial Innovation Network
- CTSA Program in Action

Clinical and Translational Science Awards (CTSA) Program

The CTSA Program is designed to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. [Learn more.](#)

Transforming Clinical and Translational Research

Turning scientific discoveries into clinical advances often is an inefficient process due to insufficient resources and too few specially trained researchers. NCATS' CTSA Program supports an innovative national network of medical research institutions – called “hubs” – that work together to improve the translational research process to get more treatments to more patients more quickly.

CTSA Program hubs collaborate locally, regionally and nationally, fostering innovation in training and research methodologies. NCATS continues to build on the strong foundation of the CTSA Program to tackle system-wide scientific and operational problems to make the clinical and translational research enterprise more efficient. [Learn more about the CTSA Program.](#)

BU CTSI



Clinical & Translational Science Institute

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Accelerating Discoveries Toward Better Health

The BU-CTSI is a 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



SUCCESS STORY



COLLABORATIVE INITIATIVE WITH NCATS & CTSA TO SUPPORT INNOVATION IN CLINICAL TRIALS

Introducing the Trial Innovation Network (TIN)

BU HAS JOINED SMART IRB

CTSA paves way for nationwide single IRB model

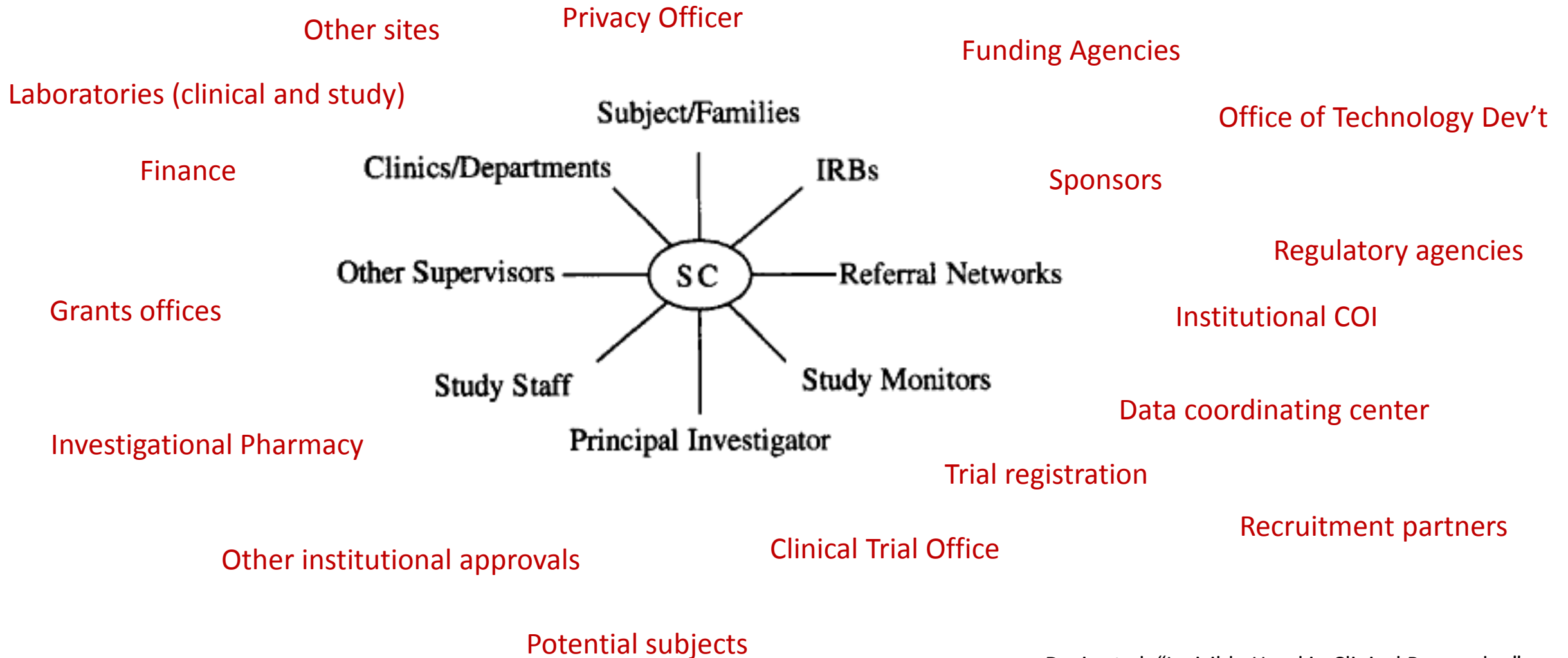
Essential role of the research coordinator

- “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

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 to 180 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...”**

The Central Position of the Study Coordinator



CTSA Coordinator Survey, 2008

- 1,590 coordinators from CTSA institutions.

A few results:

- 32% RCs responded that tasks assigned to them were inappropriate
- 55% of RCs indicated they did not receive appropriate training for all the tasks they were required to do.
- 41% RCs reported no identified opportunities for career advancement or development.

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

What is a “Research Coordinator Network”?

- “Supportive system of information exchange and/or services provided to facilitate collaboration and education of research coordinators.”
- Characterized by having one of the following:
 - Governing body, formal mission statements, or schedule of formal professional meetings.

[From Research Coordinator Networks and Support Models Among AHCs in the CTSA Consortium, survey (2013) and paper, in press]

- First CTSA-supported coordinator networks ~ 2006 (U. Iowa)
- 2013: CTSA Coordinator Taskforce distributed a CTSA-wide survey to assess support to research coordinators in CTSA institutions.
 - 37.7% CTSA institutions have a network

BU CTSI and Workforce Development

- The BMC/BU Medical Campus Research Professionals Network (RPN) 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 is to provide a professional forum for research coordinators to network and exchange ideas and develop within the profession.

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

ECRPTQ: Enhancing Clinical Research Professionals' Training and Qualifications

- Effort of CTSA 2014-2016: “Competency-based training for research personnel involved in executing clinical trials is inconsistent or absent, highlighting a critical gap to improving the conduct of clinical trials.”
- Overall goal: Ensure the translational science workforce has the skills and knowledge necessary to advance translation of discoveries.
- Two aims:
 - Streamline and standardize training in GCP across the CTSA consortium
 - Develop training program to equip a highly skilled workforce with the necessary competencies to more effectively and safely execute clinical trials
 - Identify core competencies to serve as framework for defining professional competency across the clinical research enterprise.
 - Foundation for establishing and maintaining best practices.

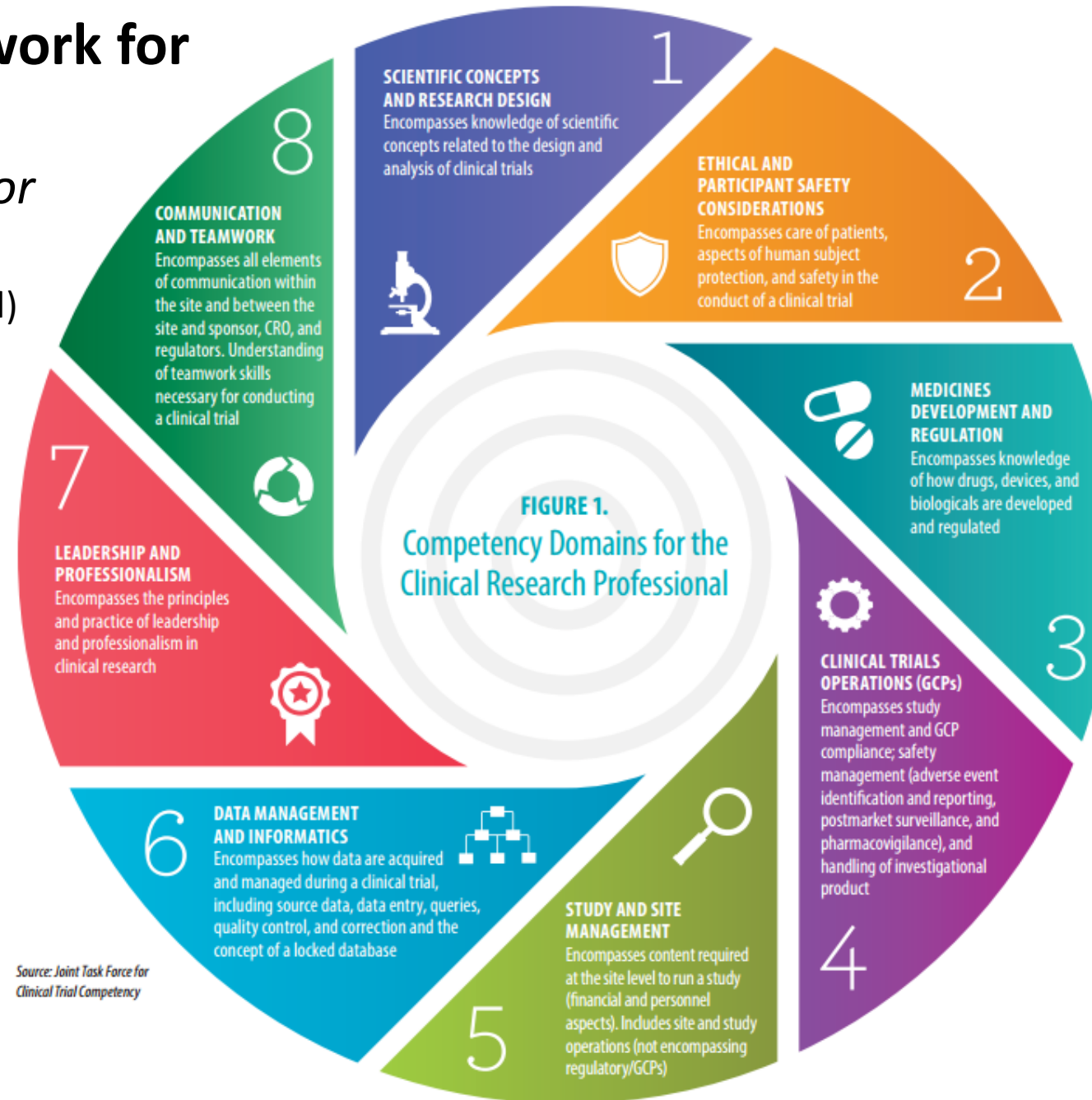
Harmonized Core Competency Framework for the Clinical Research Professional

Recommendations from the Joint Task Force for Clinical Trial Competency

(part of Multi-regional Clinical Trial (MRCT) Center at Harvard)

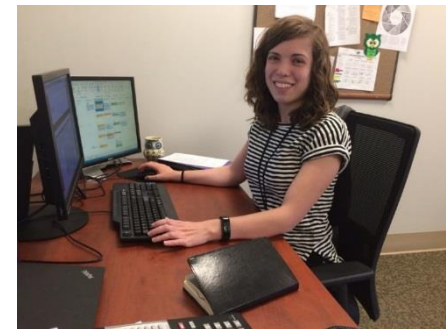
- 1) Scientific concepts and research design
- 2) Ethical and participant safety considerations
- 3) Medicines development and regulation
- 4) Clinical trials operations (GCPs)
- 5) Study and site management
- 6) Data management and informatics
- 7) Leadership and professionalism
- 8) Communication and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

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



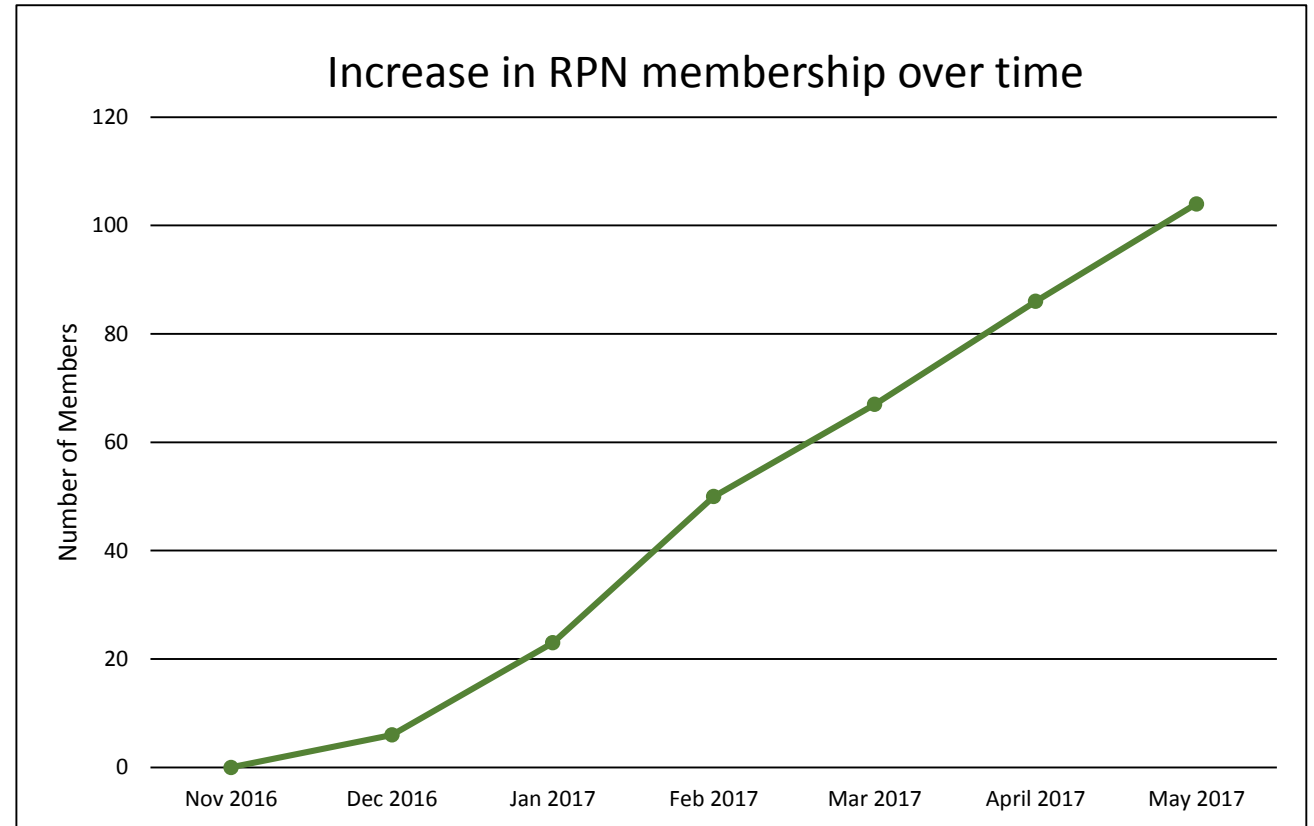
What we've done so far...

- Literature review
- Key Informant Interviews with other institutions
- Focus groups with staff at BMC/BU Medical Campus
- RPN Launch & CRRO Seminar, December 2016
- Hired Gina, January 2017



Increased membership by advertising

- CRRO Seminar December 2016
- Reminders in CRRO email communications
- CR Times articles
- Handouts at seminars, trainings
- Word of mouth



Formed a leadership committee

- Identified a group of 12 experienced and engaged research staff with varied backgrounds
- Invited to leadership committee
- Will assist/guide CRRO to develop RPN programs
- Act as 'super-users' to the resources and programs

Britte Beaudette-Zlatanova
Thomas Cheng
Ridiane Denis
Jessica Howard
Deborah McDonald
Melissa Mejia
Seville Meli
Claire Oppenheim
Jenna Sandler
Eric Stratton
Lisa Tucker
Steve Zalewski

RPN survey administered March-May 2017



37 question survey about work experiences and RPN preferences

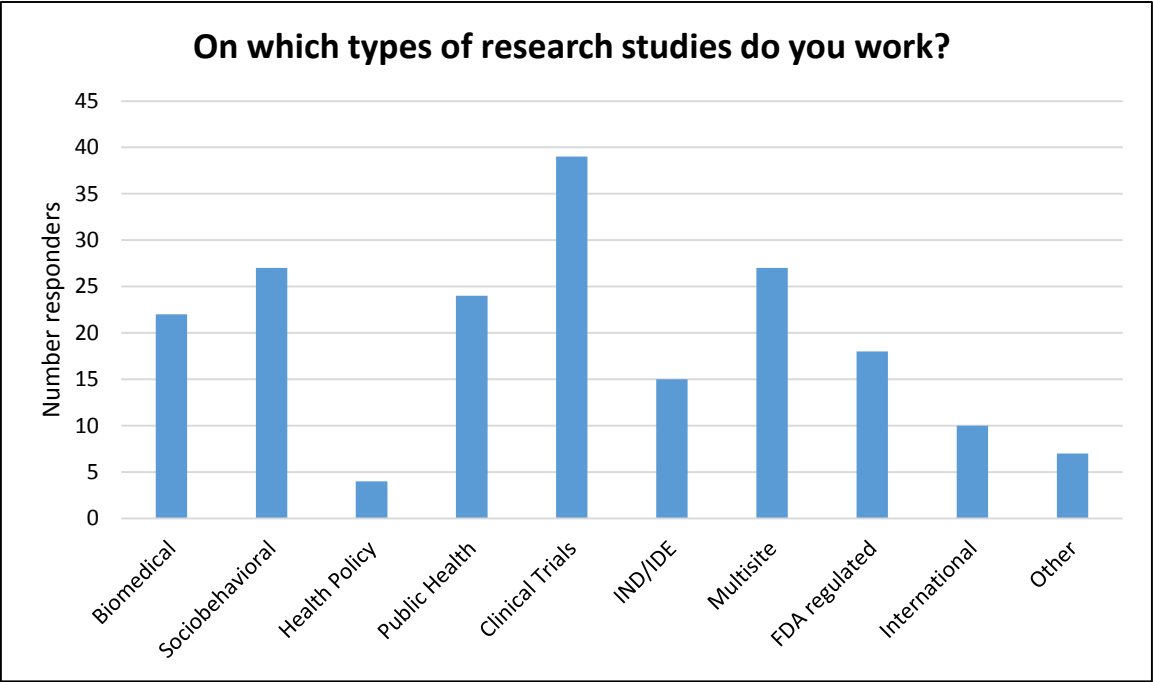
Purpose:

- Guide development of programs
- Ideas for training topics
- Gather information about job satisfaction and perception of value

Administer yearly to look at longitudinal changes within network

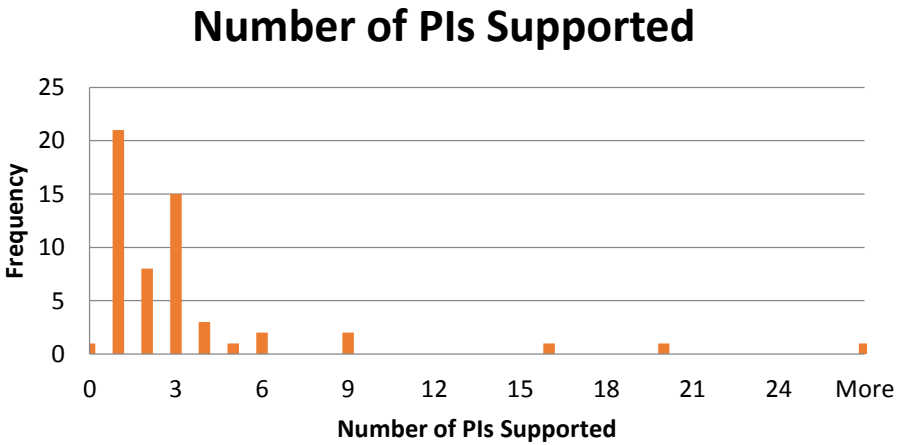
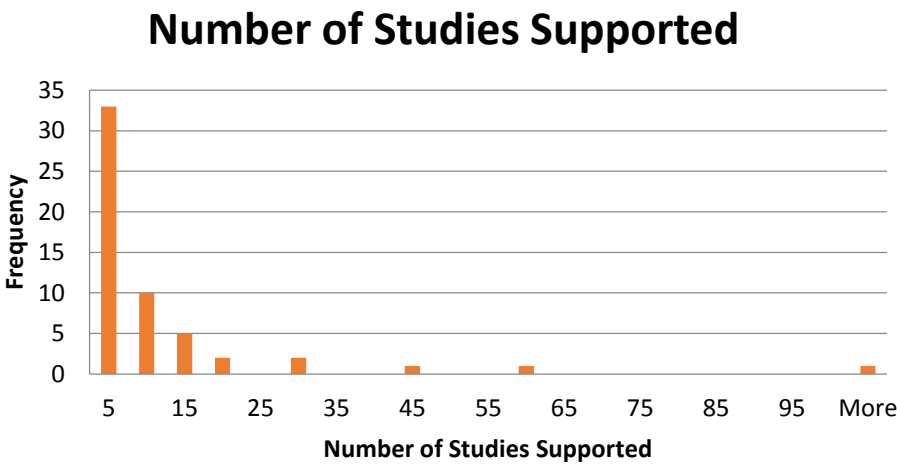
Some results!

59 responses (out of 103 members) = 57.3% response rate!



Other:

- Chart Review
- GWAS
- QI
- Educational



How would you prioritize the following potential network activities?

Potential Program Offerings	Average Ranking 0-100
Collaboration with HR to create job titles/descriptions for staff promotion/advancement	78.84
Trainings/workshops	78.55
A method to exchange resources with fellow research staff	76.00
Creation of a job bank for research staff and investigators	71.35
Developing study management tools	70.98
Educational seminars	70.89
Subcommittees tasked with identifying workplace challenges and recommending solutions/procedures/policies	64.30
Communication of institutional/federal information, policies, regulations	63.87
Mentoring program	62.98
Research staff orientation	62.24
Social networking events	56.68
Recognition events	44.41

Announcing our survey drawing winners



Thank you to everyone in the network who participated!!!!!!

Updating/Creating Study Management Tools

Updated Tools:

Eligibility Assessment Tool
Delegation/Signature Log
Individual Training Log
Group Training Log

*(updated versions now available
on CRRO website)*

Tools in Development:

Documentation of Informed Consent tool

Upcoming Tools:

Pregnancy test documentation
Regulatory binder checklist
Note-to-file template and tracking log
SOP template
Freezer temperature log
Sample collection log

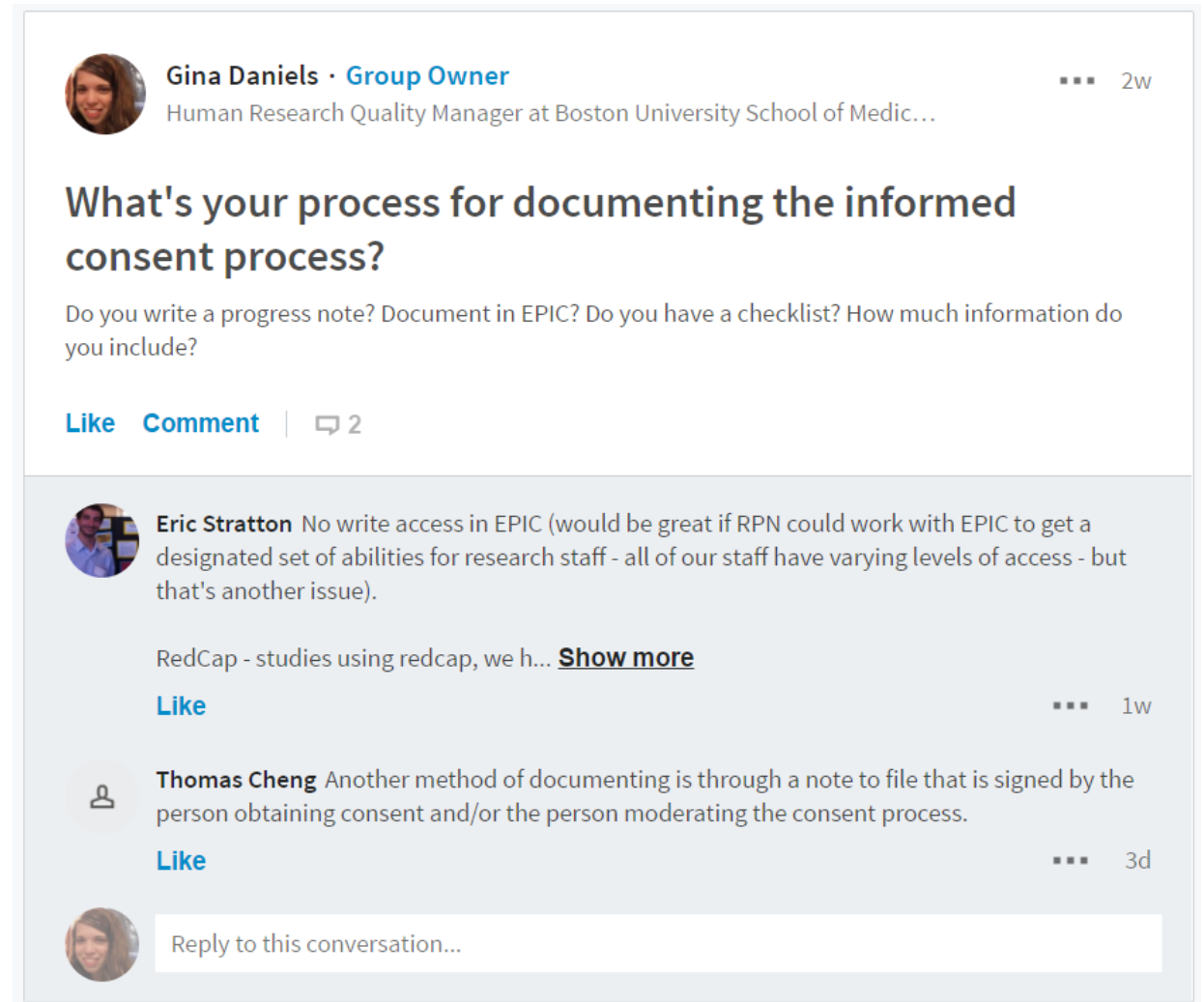
*(If you have ones that you currently use—send to Gina!
We can work together to create an official CRRO template
version!)*

NEW! Developed a discussion forum on LinkedIn

LinkedIn Group: 'BMC/BU Medical Campus Research Professionals Network'

What didn't work:

- Google Groups
- Box.com
- Yammer
- Wikiboard



The screenshot shows a LinkedIn group post from Gina Daniels, Group Owner, asking about the process for documenting informed consent. The post has two comments: one from Eric Stratton about EPIC access and RedCap, and another from Thomas Cheng about using a note to file. The post also has a 'Like' button and a 'Comment' button with a count of 2.

Gina Daniels · Group Owner
Human Research Quality Manager at Boston University School of Medic... 2w

What's your process for documenting the informed consent process?

Do you write a progress note? Document in EPIC? Do you have a checklist? How much information do you include?

[Like](#) [Comment](#) | 2

Eric Stratton No write access in EPIC (would be great if RPN could work with EPIC to get a designated set of abilities for research staff - all of our staff have varying levels of access - but that's another issue).
RedCap - studies using redcap, we h... [Show more](#)
[Like](#) 1w

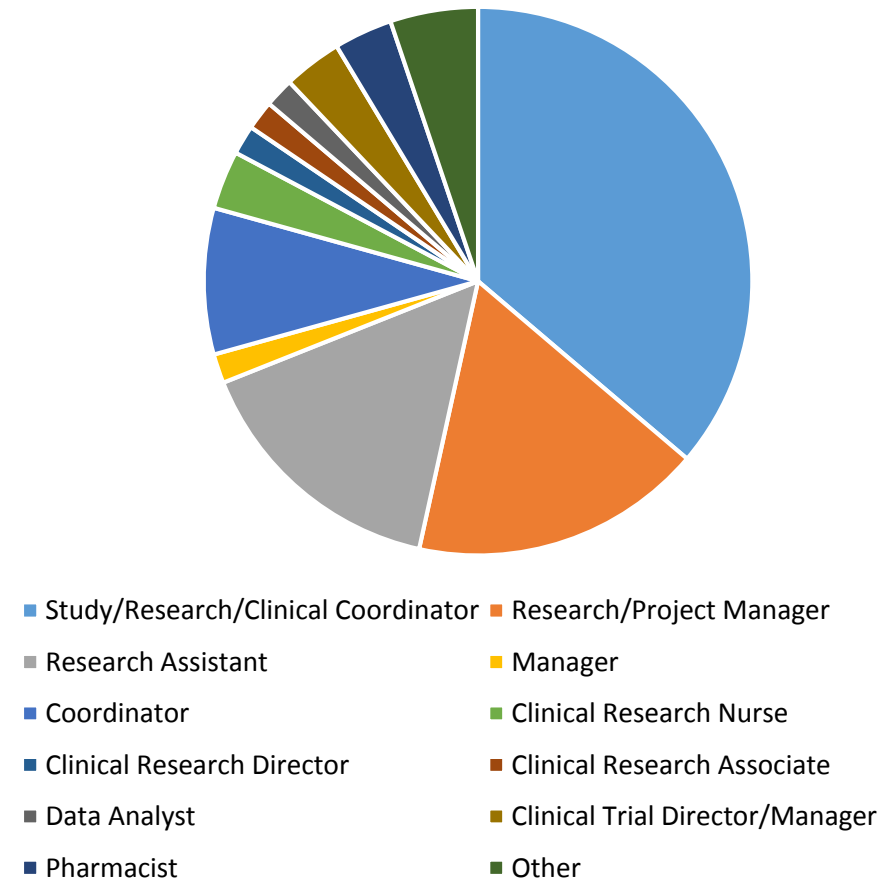
Thomas Cheng Another method of documenting is through a note to file that is signed by the person obtaining consent and/or the person moderating the consent process.
[Like](#) 3d

Reply to this conversation...

Denise Snyder visited in April 2017

- Associate Dean of Clinical Research at Duke University School of Medicine
- Created competency-based set of job descriptions for research staff
- Mapped all research staff to new job titles/descriptions
- Visited BU Medical Campus in April 2017
- Met with CRRO, BU Medical Campus HR, RPN Leadership

Research Staff Titles at BMC/BU Medical Campus



You asked and we listened! Our plans for the future...

Coordinator Curriculum Workshops

- Series of hands-on, collaborative workshops
- Peer-based learning
- Incentive for RPN members to deliver workshop, mentorship from CRRO
- Those who attend X workshops will receive certificate
- Graduation ceremony at annual RPN event

Coordinator Curriculum Workshop Topics

GCP In Practice: What Would You Do?

Professionalism in the Research Community*

Study Start-Up Timeline*

IRB Submissions: Examples, Meeting the 111 Criteria, FAQs

Budgeting Your Study

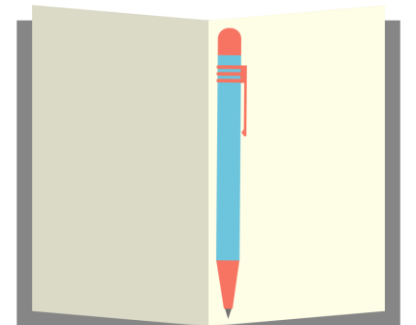
Classifying Adverse Events, Deviations, Unanticipated Problems*

Best Practices in Study Documentation*

Monitoring, Auditing, and Self-assessments

Informed Consent Workshop (extended)*

Managing a Multicenter Trial*



Onboarding Orientation

- Introduction to research at BMC/BU Medical Campus
- Explain resources, trainings, tools, seminars
- 2 hour training offered once per month

Mentoring Program

- Mentoring 'match' worksheet
- Will match mentee to mentor, based on topic
- Group mentoring sessions by topic

Support for ACRP/SoCRA certifications

- Goal: Increase % RPN members with research certifications
- Panel discussion of ACRP/SoCRA certification opportunities
- ‘Scholarships’ for our staff to pursue certification
- Room reserved for study groups



Thanks for listening!

Q & A Session with RPN Leadership

Britte Beaudette-Zlatanova, PhD – Clinical Project Manager, Renal

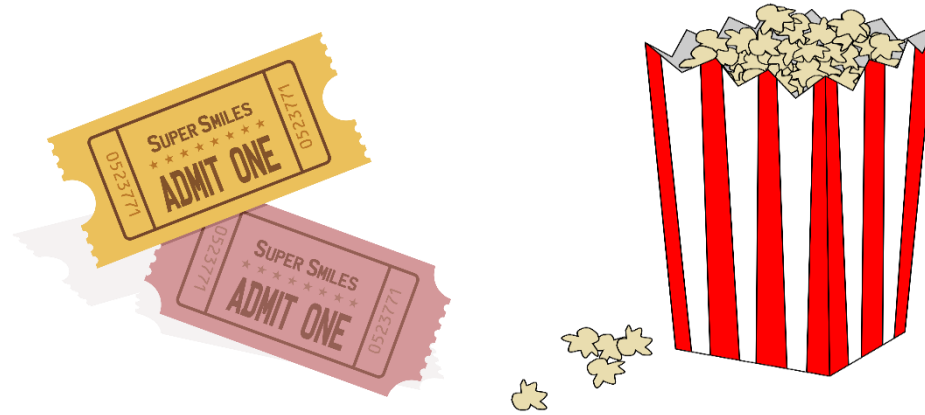
Jessica Howard, MPH – Program Director, Family Medicine

Claire Oppenheim, MPH – Research Program Manager, Psychiatry

Lisa Tucker – Regulatory and Data Coordinator, Pediatrics

Two more things:

1.



2.



Introduce yourself to at least 1 new person!