

CTTI Recommendations:
Identifying Qualified Investigators and Their Delegates to Conduct
Sponsored Clinical Trials

APPENDIX 2:

Mentoring and Knowledge-Sharing Examples

OVERVIEW

This resource is intended to serve as a reference for sponsors, contract research organizations, and site teams interested in establishing mentoring programs or knowledge-sharing networks within your organization or across a clinical trial. These types of learning activities can help you address gaps in knowledge and skills through information exchange and peer support.

Only programs designed for the clinical research industry were included, specifically those that either 1) are open to public participation or 2) share detailed information online. This list is not exhaustive, nor does CTTI endorse any of the programs or networks; rather, it is meant to illustrate how mentoring programs and knowledge-sharing networks for clinical research staff are being implemented and to provide resources for developing your own.

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MENTORING PROGRAMS

Association of Clinical Research Professionals (ACRP) Mentor Match

Mentor Match is an online tool for ACRP members to establish mentoring relationships. Mentoring is about developing others and helping them reach their goals. An essential part of being a leader in clinical research is to serve as a mentor to other clinical research professionals. Mentor Match provides ACRP members the opportunity to serve in both the capacity of mentor and mentee.

Champion: ACRP

Mentors: ACRP members who have volunteered their time to support other members' careers

Users: ACRP members who wish to pursue mentoring relationship

Approach: Members can search among registered mentors using specified criteria to find individuals whose experience and expertise match areas in which they wish to be mentored. Likewise, registered mentors can search for and identify potential mentees.

Goal: To support ACRP members in growing professionally and networking with fellow members.

Impact: No information available

Further information available at: <https://www.acrpnet.org/membership/mentor-match/>

Institute for Clinical Research Education (ICRE) Mentoring Network

Promoting education and research in clinical and translational science across the career pipeline, ICRE is the home for the University of Pittsburgh's premier clinical and translational research training programs as well as the home for the Research Education and Career Development Core. This site provides resources for mentees and mentors at every stage and explores topics such as deciding on the right mentoring model, communicating effectively, giving and receiving feedback, and finding strategies for problem solving.

Champion: University of Pittsburgh

Mentors: Professionals with research experience at the University of Pittsburgh and Carnegie Mellon University

Users: Not stated

Approach: The 'Search for a mentor' function lets mentees refine their search parameters for mentors. Mentees then reach out and design a mentoring plan by using the site's resources and tools to design a successful mentor/ mentee relationship.

Goal: To provide resources for mentees and mentors to develop, implement, and complete a successful mentoring relationship

Impact: No information available

Further information available at: <https://www.icre.pitt.edu/mentoring/>

Professional Mentoring Skills Enhancing Diversity (PROMISED)

Promoting education and research in clinical and translational science across the career pipeline, ICRE is the home for the University of Pittsburgh's premier clinical and translational research training programs as well as the home for the Research Education and Career Development Core. The PROMISED program expands participants' career coaching, leadership, and mentoring skills to help them more effectively mentor scientists who belong to underrepresented groups, as defined by the National Institutes of Health (NIH).

Organizer / Funder: NIH and the National Research Mentoring Network (NRMN)

Mentors: Mentors at the late assistant professor rank (at least 5 years in rank or equivalent) or above

Users: Not applicable

Approach: PROMISED offers an innovative, no-cost program that combines 1) three-day career coach training in Pittsburgh for mentors passionate about helping mentees drive their careers forward and 2) a series of one-month, online training modules, focused on helping mentors develop a range of critical leadership skills.

Goal: To gain leadership and career coaching skills, and be a better mentor. A certificate in leadership, as well as recognition as a National Research Mentoring Network (NRMN) Fellow, are awarded to fellows who complete both components of the program.

Impact: No information available

Further information available at: <https://www.icre.pitt.edu/promised/promised.html>

National Research Mentoring Network (NRMN)

The NRMN is a nationwide consortium of biomedical professionals and institutions collaborating to provide all trainees across the biomedical, behavioral, clinical and social sciences with evidence-based mentorship and professional development programming.

Champion: National Institutes of Health (NIH) Diversity Program Consortium

Mentors: Highly knowledgeable and skilled mentors from various disciplines

Users: Diverse mentees from the undergraduate to early career faculty level (undergraduate students, graduate students, postdocs, faculty, non-faculty researchers, program directors, disciplinary, and professional & institutional leaders)

Approach: NRMN aims to utilize structured mentorship and networking experiences to enhance the training and career development of individuals from diverse backgrounds, communities, and cultures who are pursuing biomedical and behavioral research careers.

Goal: To enhance the diversity of the NIH-funded research workforce

Impact: No information available

Further information available at: <https://nrmnet.net/about-nrmn-2/>

Doris Duke Charitable Foundation (DDCF) Clinical Research Mentorship

The Clinical Research Mentorship program provides previously funded Doris Duke investigators the opportunity to foster the next generation of clinical researchers by mentoring a medical student for one year.

Champion: DDCF

Mentors: Past and current Doris Duke-supported researchers

Users: Medical students (recommended that students be in the third year of medical school)

Approach: Past and present principal investigators on medical research grants from DDCF identify a medical student to mentor for one year and then apply as a team. Alternatively, medical students identify a qualifying DDCF principal investigator and they apply together.

Goal: Mentor and mentee work on a research project together over the course of one year.

Impact: No information available

Further information available at: <http://www.ddcf.org/what-we-fund/medical-research/goals-and-strategies/encourage-and-develop-clinical-research-careers/clinical-research-mentorship/>

University of California Davis (UCD) Clinical Research Coordinator Mentoring Program

The Clinical and Translational Science Center (CTSC) Clinical Research Coordinator (CRC) Mentoring Program is a one-on-one mentoring program for UCD Clinical Research Coordinators and other research staff in a CRC functional role. Priority is given to those participating in FDA-regulated clinical trials with drugs, devices or dietary supplements. The program is provided for a maximum of 10 hours of face-to-face training with a CTSC mentor.

Champion: UCD CTSC

Mentors: UCD Clinical Research Coordinators

Users: UCD Clinical Research Coordinators and other research staff in a CRC functional role; priority is given to those participating in FDA-regulated clinical trials with drugs, devices or dietary supplements.

Approach: The program is provided for a maximum of 10 hours of face-to-face training with a CTSC mentor. A 'Coordinator Competencies Checklist' (CCC) is used to evaluate completion of assigned training or tasks.

Goal: To close all of the identified knowledge / performance gaps from the CCC over the course of 10 hours

Impact: No information available

Further information available at:

<https://www.ucdmc.ucdavis.edu/clinicaltrials/Training/Mentoring.html>

Lymphoma Clinical Research Mentoring Program

The focus of the Lymphoma Research Foundation (LRF) Lymphoma Clinical Research Mentoring Program (LCRMP) is to enhance the ability of LRF scholars to successfully design and administer clinical research studies and apply for grants to support related lymphoma research. The program is two years in length and offers a broad education on clinical research and career development as well as managing career and quality of life issues.

Champion: LRF

Mentors: Mentor from mentees home institution who is willing and able to provide financial support for the project and demonstrate a commitment to completing the proposal

Users: Hematology/oncology fellows and junior faculty with a focus on clinical research in lymphoma (Applicants should not be more than four years beyond completion of their fellowship or more than 12 years beyond completion of their MD or equivalent degree.)

Approach: The program will emphasize training in clinical research methods and design, statistical analysis, pathology, incorporating and interpreting correlative studies into clinical trials, and grant submission and funding. The program also aims to foster mentorship and research collaboration among experts and trainees in the field.

Goal: Over the course of two years LRF scholars will enhance their ability to successfully design and administer clinical research studies and apply for grants to support related lymphoma research.

Impact: No information available

Further information available at: <https://www.lymphoma.org/wp-content/uploads/2018/03/LCRMP-RFP-2018-FINAL.pdf>

Society for Clinical Research Sites (SCRS) Mentoring Program

SCRS fosters an environment and culture amongst its members that encourages teaching and knowledge sharing. The SCRS community is strengthened by members who share their tremendous experience and knowledge with those just beginning their clinical research journey or encountering situations for the first time.

Champion: SCRS

Mentors: SCRS members who have volunteered their time to support other members' careers

Users: SCRS members who wish to pursue mentoring relationships

Approach: Recognizing both the importance of SCRS' emphasis on excellence and the reality that new sites enter the industry each day, site members will offer mentoring to other site members.

Goal: The goal of SCRS' mentorship pillar is to facilitate continued development of the site community to strengthen the voice of all sites. Providing opportunities and methods for mentorship enhances the unified vision of all sites to treat study participants in the most effective way possible.

Impact: SCRS mentorship infuses the site landscape with more developed, knowledgeable and prepared sites that are as efficient and prepared as possible for the ever-changing challenges of the industry.

Further information available at: <http://myscrs.org/24-revision-v1/mission/>

MENTORING PROGRAMS DESCRIBED IN THE LITERATURE¹

¹ The articles in this section were identified through a web search, not a systematic review of the literature.

Training the Next Generation of Research Mentors: The University of California, San Francisco (UCSF) Clinical & Translational Science Institute Mentor Development Program

The University of California, San Francisco (UCSF) Clinical & Translational Science Institute (CTSI) Mentor Development Program (MDP) was established to train the next generation of clinical and translational research mentors.

Champion: UCSF and National Institutes of Health (NIH)

Mentors: Eligible mid-career and early senior clinical and translational research faculty at UCSF. Eligibility includes having dedicated research time, expertise in a scientific area, and a desire to be a lead research mentor for one to three junior faculty.

Users: Junior faculty at UCSF

Approach: The curriculum consists of 10 case-based seminars held during monthly half-day meetings over a five-month period. The monthly schedule includes two seminars each morning and time for Mentors-in-Training (MITs) to network with each other and with senior mentors. An MDP wiki site was developed that includes mentoring resources, seminar outlines, illustrative mentoring cases, and the opportunity to add observations and comments to the mentoring cases. Seminars are recorded and available for viewing on DVDs, creating an online resource for the entire UCSF community. Mentees have a mentoring team consisting of different types of mentors, each with distinct roles. The key to the mentoring team is the lead mentor, who is responsible for developing the creative and independent research career of his or her mentee.

Goal: The primary goal of the MDP is to train mid-career and early senior clinical and translational research faculty in the knowledge and art of mentoring so that they can more effectively mentor the next generation of clinical and translational researchers.

Impact: A post-MDP survey measured the program's impact on enhancement of five key mentoring skills, change in the Mentors-in-Training (MIT) self-rated importance of being a mentor to their career satisfaction, and overall confidence in their mentoring skills. Overall, 96% of MITs felt that participation in the MDP helped them to become better mentors. A majority reported a significant increase in confidence in mentoring skills and most reported an increased understanding of important mentoring issues at UCSF.

Further information available at: <https://ascpt.onlinelibrary.wiley.com/doi/full/10.1111/j.1752-8062.2009.00120.x>

Developing a Mentorship Program for Clinical Researchers

This is a case study review of the role of mentors in developing and sustaining clinical investigators at the Cleveland Clinic.

Champion: Cleveland Clinic

Mentors: A clinical research mentor is a member of the staff who advises or guides a colleague in matters relating to clinical research.

Users: Clinician scientists and clinician investigators. A clinician scientist is a medical doctor (MD) or an MD with a doctorate in philosophy (PhD) who directs laboratory-based basic research and has limited clinical responsibilities. A clinician investigator is an MD, a PhD-prepared registered nurse (RN), a pharmacist with a doctorate in pharmacy (PharmD), or a dentist with a doctorate in either dental surgery (DDS) or medical dentistry (DMD) who conducts research with study participants regardless of time devoted to clinical responsibilities.

Approach: The Mentor Development Program was created in 2004 to provide mentors and protégés at the Cleveland Clinic an opportunity to share experiences and cultivate mentoring skills. The hope is that the mentoring program and the code of mentorship will ensure that a new cadre of independent clinical researchers will become tomorrow's clinical research mentors, but the program is new and thus has not been evaluated.

Goal: The successful mentor-protégé relationship enhances the protégé's research experience by improving the caliber of the research and assisting the process of promising researchers achieving their goals of becoming independent investigators.

Impact: The increased number of NIH career development K awards at the Cleveland Clinic supports the effectiveness of this program.

Further information available at: <https://onlinelibrary.wiley.com/doi/pdf/10.1002/chp.105>

Developing a Successful Peer-to-Peer Mentoring Program

Network of Networks (N2) mentoring program aims to fill a gap between formal research education and the application of this formal education into daily practice. There is a need for a cost-effective mentoring program that can pair seasoned research professionals with those who are less seasoned and in need of developing skills. N2 is a not-for-profit collaboration of healthcare organizations and other stakeholders in Canada that conduct clinical research involving human subjects. N2 is a national initiative that aims to enhance Canada's research capability and capacity, whose membership includes over 200 clinical research sites across Canada.

Champion: N2

Mentors: Research professionals who have at least five years' experience in clinical research as well as expertise in a particular area of clinical research who are interested and available to provide mentoring to less seasoned clinical research staff.

Users: Research professionals who are in need of developing new skills in conducting clinical research

Approach: Both mentor and mentee participants are required to complete an application form (demographic and contact information, area of research expertise, therapeutic area, and number of years of experience in research). Mentor applicants are asked to check a list of areas of expertise in which they can provide mentoring. Mentee applicants are asked to check a list of areas in which they would like to receive mentoring. The mentoring committee reviews the applications and pairs participants. The mentoring committee recommends a period of three-to-four months for the mentoring relationship, with the belief that having a clear endpoint would make the mentor/mentee pair more productive.

Goal: The goals of the mentoring program are to facilitate a national, institutional mentoring program by pairing volunteer mentors with more junior colleagues for a four-month period, to develop a roster of mentors along with their areas of expertise, to develop a process by which mentees will be paired with appropriate mentors, and to obtain feedback from both the mentor and mentee about their experience.

Impact: The goals of most mentor/mentee pairings had been achieved by three months. A survey link was sent via e-mail to the 18 participants, both mentors and mentees, who had completed the mentoring program. Seven participants responded to the survey, which gave a response rate of 39%. The survey asked participants to rate their overall experience on a scale of 1 to 10 (10 being excellent). The average rating was 8.8 with a range of 8 to 10.

Further information available at: <http://www.appliedclinicaltrials.com/developing-successful-peer-peer-mentoring-program?pageID=1>

Mentor Training for Clinical and Translational Researchers

The training materials included in this curriculum build on a set of core competencies and learning objectives, and at the same time offer flexibility for facilitators to introduce multiple types of group activities and assignments for participants to apply what they have learned in their mentoring practices. The curriculum format is designed to promote peer learning guided by discussion of provocative mentoring dilemmas that promote reflection of one's mentoring philosophy and practices.

Champion: University of Wisconsin-Madison

Mentors: Academic research mentors in clinical and translational science. Originally developed for the primary research mentors of senior post-docs and junior faculty engaged in some aspect of clinical and translational research, the curriculum as a whole is designed to include activities relevant to a broad range of mentors across diverse areas of research and varied stages of their mentoring relationships.

Users: Not applicable

Approach: The approach described provides mentors with an intellectual framework, an opportunity to experiment with various methods, and a forum in which to solve mentoring dilemmas with the help of their peers. The mentor training process expands each mentor's experience through secondhand exposure to the experiences of the entire group, enabling participants to engage with as many mentoring experiences as each of them would typically handle in a decade. This process in turn enhances their readiness to work with diverse mentees and anticipate new situations

Goal: The goal of the curriculum is to accelerate the process of becoming an effective research mentor. At the completion of the training, mentors will have articulated their own approach to mentoring and have a toolbox of strategies to draw upon when confronted with mentoring challenges.

Impact: No information available

Further information available at:

<http://health.usf.edu/medicine/mdprogram/rise/scholarsresources/~media/FBB05459BD6B4396BB76725C85BAFF9E.ashx>

KNOWLEDGE SHARING AND CAREER DEVELOPMENT

Oregon Health & Science University (OHSU) Clinical Research Coordinator Network

The Clinical Research Coordinator Network (CRCN) fosters networking, professional development and learning opportunities by acting as a platform for sharing information, ideas and best practices among coordinators and other research staff.

Champion: OHSU

Structure: The online network allows members to access tools, templates and materials from past meetings, stay updated about educational opportunities and events, ask questions and join discussions with other coordinators, and find professional resources across OHSU and beyond.

Users: Clinical Research Coordinators at OHSU and associated institutions

Goal: Foster networking, professional development, and learning opportunities

Impact: No information available

Further information available at: <https://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/sc-network.cfm>

University of Florida (UF) Clinical & Translational Science Institute (CTSI)

The CTSI Translational Workforce Development Program offers opportunities for Clinical Research Coordinators (CRCs) to engage, interact, and learn.

Champion: UF CTSI

Structure: The program provides:

- ▶ A knowledge-sharing portal for CRCs to engage, interact, and learn
- ▶ Facilitated study groups for CRCs seeking national certification (ACRP and SoCRA) in clinical research coordination
- ▶ A six-month Research Coordinator Leadership Development Program with monthly two-hour sessions designed to develop the next generation of leaders in the field of research coordination
- ▶ The Clinical Research Professionals Advisory Council, a diverse group of clinical research professionals from a variety of departments who promote cross-functional collaboration for research initiatives at UF. The council's goal is to help CRCs grow professionally and to achieve success at UF by being champions for clinical research, and facilitate collaborative discussion forums to exchange information.

Users: UF CRCs

Goal: The program helps CRCs grow professionally and achieve success by being champions for clinical research, facilitates collaborative discussion forums to exchange information, and provides a connection between CRCs and functional units involved with clinical research.

Impact: No information available

Further information available at: <https://www.ctsi.ufl.edu/education/research-coordinators/>

University of Washington Institute of Translational Health Sciences (ITHS)

The ITHS Research Coordinator Networking to Enhance Development (NED) Conference is an annual, day-long professional development conference for research coordinators held in Seattle.

Champion: University of Washington

Structure: Participants attend general sessions and choose relevant breakout sessions to expand their knowledge and skills during the day-long conference.

Users: Research professionals of all levels of experience who perform research coordination duties in the health sciences field at: Fred Hutchinson Cancer Research Center, Harborview Medical Center, Seattle Cancer Care Alliance, Seattle Children's Hospital, and the University of Washington

Goal: Provide a networking and knowledge sharing opportunity for research coordinators in the Seattle area. Past NED materials are posted online for reference.

Impact: No information available

Further information available at: <https://www.iths.org/education/professional-development/rc/annual-research-coordinator-ned-conference/>

University of California San Francisco (UCSF) Clinical Research Coordinators Council

The Clinical Research Coordinators (CRC) Council's goal is to serve as an ongoing forum for networking and resource sharing within the clinical research community at UCSF.

Champion: UCSF

Structure: The Council is comprised of representatives from a variety of departments.

Users: UCSF CRCs

Goal: To advocate professional development opportunities for the CRC community, offer insight to senior leadership about workflows in order to help strategize training plans for all CRCs, provide a connection between CRCs and functional units involved with clinical research, and identify and disseminate best practices within the CRC community.

Impact: No information available

Further information available at: <https://irb.ucsf.edu/clinical-research-coordinators-council>

A Knowledge Management Framework and Approach for Clinical Development

A knowledge management (KM) framework enhances knowledge gathering, sharing, application, and retention within clinical development and enables the effective and successful implementation of a clinical quality management system (QMS). This paper outlines in general terms key elements of a clinical knowledge management (CKM) framework to assist clinical development organizations in understanding its benefits and basic components. Ideas are provided at a high level for flexible approaches and solutions aimed to enhance knowledge gathering, sharing, application, and retention within clinical development.

Purpose: The intent of the CKM framework is to enable development of an organization-specific CKM program to retain, share, and apply the most valuable knowledge (as defined by the organization) and make it available to people as needed. An effective CKM strategy involves consistent approaches for connecting people to knowledge and people to each other to leverage existing content and experience.

Champion: TransCelerate

Structure: The CKM framework includes two foundational building blocks (Culture and Continuous Improvement) and four supporting pillars (People, Business Processes, Content, and Technology). A four-step approach can be used to develop and implement a CKM program based on the framework described above and repeated to sustain and improve the CKM strategy over time. The time and resources required for each step vary depending on the organizational needs and desired outcomes.

Users: Not specified

Goal: A key goal of the CKM program is to enable continuous learning, improvement, and innovation in the business. The goal of managing knowledge is to improve organizational performance by getting the right information to the right people at the right time.

Impact: No information available

Further information available at:

<http://journals.sagepub.com/doi/pdf/10.1177/2168479016664773>

The examples presented were identified through a web search using a combination of the following keywords:

- ▶ clinical research coordinator
- ▶ knowledge-sharing network
- ▶ clinical research coordinator mentoring
- ▶ how to create a mentoring program in a clinical research organization
- ▶ clinical research mentoring for investigators
- ▶ knowledge sharing in the clinical research industry

Only programs designed for the clinical research industry were included, specifically those that either 1) are open to public participation or 2) share detailed information online.