Curriculum for DaCCoTA Professional Development Core Awardees

Goal: The Professional Development Core seeks to build an integrated program of education, career development and training opportunities to support the DaCCoTA. While there is currently a foundation for such activities, we propose significant improvements through the sharing of expertise and programs, as well as by cooperatively creating additional curricula and using novel approaches to maximize resources. All of the partner institutions have extensive expertise with NIGMS-funded IDeA programs (COBRE, INBRE). These programs have provided a model to build mentored career development programs. One of the innovative approaches to be used in the DaCCoTA to train awardees (K awardees) involves interdisciplinary approaches. This award has paired scientists and clinicians from different backgrounds and involves students in projects that are team-based and team-mentored. The interinstitutional interactions will foster collaborations resulting in the formation of new interdisciplinary teams that are required for solving complex medical issues, especially those related to cancer biology. The primary objective of this core is to enhance our institutions' strengths in education, training and mentor development through the creation of an integrated program administered by the DaCCoTA to develop successful clinical and translational cancer research investigators.
All of the training modules/experiences are open to all faculty/students/post-doctoral fellows. Pilot grant awardees are also strongly encouraged to participate.

Training for Trainees and Mentors:

A. Core Set of Training: These training experiences are mandatory for those conducting research involving human subjects or animals. These training exercises can be taken at the "home" institution of the trainee/mentor.

a. IRB/IACUC Training: All participants whose research experience will involve the use of animals will be required to complete an online course for the care and use of laboratory animals (AALAS Learning Library course), and those that are conducting research with human subjects will be required to complete an online course and pass an exam for working with human subjects.

Time of Training: Training needs will be identified during the "Inquiry" phase and must be completed successfully prior to submitting applications for consideration of funding.
Who Needs this Training: All investigators involved in animal/human research. IACUC training is required for those conducting research involving animals and IRB training is required for those conducting research involving human subjects/tissue.
Format/Subject Matter: This training will consist of online modules through the CITI program at each participating institution. All participants will be required to complete the course (based upon need) and pass the online exam associated with each module before being allowed to work with laboratory animals and/or human subjects. For participants that do not have access to these modules (e.g., some community engagement PIs), access to an institutional CITI program will be provided.

The modules in the course cover IACUC roles, regulations regarding animal research, alternatives to the use of animals in research, USDA pain/distress categories, surgery and anesthesia, using toxic and hazardous agents, endpoint criteria and euthanasia, reporting misuse, mistreatment or non-compliance, and occupational health and safety. Participants whose research will involve human subjects or tissues will be trained in the basics of IRB regulations and the review process, assessing participant risks, avoiding harm, conflicts of interest, cultural competence, FDA-regulated research, HIPAA-regulated research, genetic research, informed consent, international research, internet research, the responsibilities of the IRB, records-based research, research in schools,

research with protected populations, research with vulnerable subjects, unanticipated problems and reporting, and students in research. The IRB monitors completion of this course and will notify the mentor when it has been completed. All participants associated with projects supported by federal funding are required to undergo conflict of interest training. This CITI-based course provides modules in conflict of interest and has a quiz that must be passed. Completion of the course is monitored by the appropriate university's Office of Research and Sponsored Programs. The Director of the Core will be notified if a trainee is not in compliance.
Duration and Frequency: Research topic-specific training (i.e., IRB, IACUC) will occur once unless the participant's certification expires prior to completion of the project. Since these courses are online modules, duration of the training will be trainee dependent.
Mentor Participation: All faculty mentors must also participate in their institution's IRB/IACUC training programs/modules.

b. <u>Responsible Conduct in Research (RCR):</u> This training ensures trainees are conversant with the principles of scientific integrity and proper conduct of research in various venues and using different approaches. Trainees will receive informal training from faculty and mentors, and formal training through workshops.
Time of Training: Year 1.
Who Needs this Training: All trainees conducting research using human subjects or animal models. Mandatory for Clinical and K Awardees.
Format/Subject Matter: RCR training consists of participation in an annual 2.5-hour workshop entitled "Ethics in Research" that meets face-to-face on the USD campus. It is also acceptable for the trainee to participate in the CITI course for RCR at their particular home institution during the first year.
Duration and Frequency: One-time training for RCR.
Mentor Participation: One-time requirement for mentors.

c. <u>Annual DaCCoTA Symposium:</u>
Time of Training: Yearly.
Who Needs this Training: All participants in the DaCCoTA are required to attend the annual meeting.
Format/Subject Matter: The annual meeting of the DaCCoTA provides an opportunity for all engaged in clinical/translational research (CTR) to present and interact with others with common interests. It allows investigators to participate in workshops and present their research data. The objectives of the annual meeting are to increase the participants' awareness of the principles of CTR, to understand the ethnic disparities in cancer-related research in North and South Dakota, to identify the resources available to investigators within the DaCCoTA network, to help participants understand the availability and regulatory requirements of grants and research within the DaCCoTA and to provide mentors with the skillset for successful mentorship.
Duration and Frequency: Yearly for all members.
Mentor Participation: All faculty mentors are required to attend and may be involved in training workshops.

d. Regular Meetings with Core Directors:
Time of Training: For the duration of the award.
Who Needs the Training: All who receive funding through the DaCCoTA.
Format/Subject Matter: The purpose of these meetings is to discuss progress related to the research, any potential pitfalls encountered with research/mentoring, suggestions for modifications in research direction (if applicable), referrals to resources and other

cores in the DaCCoTA, new opportunities available regarding grants/methods/techniques/equipment, and any other concerns by the core directors/participants relevant to research and/or career development.
Duration and Frequency: Twice per year.
Mentor Participation: The mentor will not be involved in initial meetings with the awardee but may be involved as needed or in regularly scheduled meetings to discuss research progress and/or any modifications that may be necessary. Separate meetings with the mentor may be scheduled if there are concerns raised with regards to research progress and/or mentorship.

B. Supplementary Training: For the Clinical Research Opportunities Program Awardees, at least two of the following ten modules must be taken by the trainee during the training period. **For the K Awardees**, at least six of the following ten modules must be taken by the trainee during the training period. For the mentors, one mentoring module must be taken in a three-year period.

The following modules can be taken through the University of Minnesota Online Research Training program. A University of Minnesota Guest Account can be set up by completing this form: https://my-account.umn.edu/create-guest-acct. You will be led through a process for creating a username and password. Once you have completed this, you can use your guest account to sign into the University of Minnesota's Training Hub: training.umn.edu. This is part of the Minnesota Clinical and Translational Science Institute.

a. CST001: Enhancing Motivation using the CARES mentoring model. In this online training module, you will learn about basic motivation concepts and their well-researched impact on satisfaction, performance and persistence in educational and professional settings. This module is targeted to faculty that are mentoring students, fellows and/or other faculty in academic settings including research training programs.

b. CTS101: Optimizing the practice of mentoring 101. In this online training module, you will learn about the value of mentoring and explore strategies for supporting your mentees' intellectual, professional and psychosocial development as researchers. You will be introduced to different phases in the lifecycle of a mentoring relationship, and you will be encouraged to adopt a thoughtful, proactive approach to navigating challenges that might arise in your interactions with mentees.

c. CTS004: Participant recruitment and retention. This online, interactive course will provide you with a common, realistic example of a successful recruitment and retention process from the CRC perspective. Upon successful completion of this course you will be able to begin developing successful recruitment plans for clinical trials.

d. Research Ethics. Ethics in Clinical Research provides a brief history and an introduction to ethical issues that pertain to clinical research. This short module will help you to anticipate and prepare for points during clinical research at which ethical challenges may surface.

e. CTS008: Basic statistics for clinical research. This course provides a basic overview of the role that statistical procedures play in the design and implementation of clinical research, the purpose of which is to derive outcomes that can help improve the lives of people and populations.

f. CTS010: Introduction to epidemiologic methods. This course provides an overview of the epidemiologic methods that influence the design and implementation of clinical research.

g. HRP200: Ethics and human subject protection. Complementing Good Clinical Practice: An Introduction to ICH GCP Guidelines. This course takes a dive into the ethical considerations facing clinical research professionals and enables them to put the rules into

practice to ensure human subject safety and well-being at all times. This course does NOT fulfill the IRB training requirements.

h. **HRP309: Improving recruitment, accrual and retention in clinical trials.** This course provides best practices to help your clinical research site assess how to better communicate with potential participants and begin a critical reflection of your own skills and organizational practices to improve recruitment and retention with a focus on operational efficiency, cultural competency and patient centricity.

i. **HRP510: Risk-based monitoring: the essentials for investigators**. As an investigator, do you know what risk-based monitoring (RBM) means to you and your trial staff? This interactive eLearning course answers the fundamental questions: What is RBM and how is it different from the standard monitoring approach? It also examines the impact on investigators specifically, including new approaches to data management, study budget and contract considerations.

j. **Grant Writing.** The goal of this workshop is to provide trainees with the tools and understanding of how to craft a competitive grant proposal. Trainees will be introduced to how to read and interpret requests for grant applications, different types of extramural awards from a variety of agencies, resources for assistance, scientific review and scoring mechanisms and regulatory requirements. Trainees will participate in mock study sections to gain experiences with how to review grants, how to fashion revised grants and how to score grants. As they move through this workshop, which will involve 2 semesters, the trainee will begin drafting their own R01 application, while receiving feedback from other scholars and workshop leaders. Samples for modules involving grant writing practices can be found through the following link: https://diamondportal.org/do/search/?q=grant%20writing&start=0&context=12268604&facet=.