ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA)

2023 Mentor Handbook

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: CAREER DEVELOPMENT AWARD

MENTOR HANDBOOK

TABLE OF CONTENTS

SECTION 1

ABOUT THE ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: CAREER DEVELOPMENT AWARD PROGRAM (Winn CDA)

PROGRAM SUMMARY & BACKGROUND

Bristol Myers Squibb Foundation (BMSF) and Virginia Commonwealth University (VCU) have created the Robert A. Winn Diversity in Clinical Trials Award Program to increase the diversity of patients enrolled in clinical trials, and ultimately to improve public health through the development of therapeutics for all populations. The initiative consists of a Career Development Award (Winn CDA) program for early-stage clinical investigators and a Clinical Investigator Pathway Program (Winn CIPP) for medical students. It provides emerging investigators the sponsorship, support, and tools they need to conduct clinical trials that will yield new treatments effective in all populations.

The Winn CDA is a 2-year program designed to support the career development of early-stage investigator physicians (as defined by NIH), who are underrepresented in medicine or who have a demonstrated commitment to increasing diversity in clinical research. The program prepares them to become independent clinical trial investigators who are engaged in advancing health equity through their research and mentoring. The Winn CDA offers a comprehensive and integrated approach to increasing diversity in clinical trials through workforce development and clinical trial site development in underserved communities where underrepresented patients receive care. Additionally, the program will assist program investigators in building capacity and standing up new clinical trials sites in communities with diverse and heavily burdened patient populations.

KEY PROGRAM PARTNERS AND SUPPORTERS

BRISTOL MYERS SQUIBB FOUNDATION

The Bristol-Myers Squibb Foundation (BMSF) is committed to improving the health outcomes of populations disproportionately affected by serious diseases by strengthening healthcare worker capacity, integrating medical care and community-based supportive services, and addressing unmet medical needs. Bristol Myers Squibb, BMSF's sole funder, recognizes the need to take concrete steps to better serve and collaborate with an increasingly diverse US population and underserved communities around the world. This is achieved in part through BMSF, which supports community-based programs that promote cancer awareness, screening, care, and support among high-risk populations. BMSF aspires to be at the center of a vibrant healthcare innovation ecosystem, where academic research centers, biotech and biopharma companies all contribute to continued scientific advancement. The commitment of BMS and BMSF to Health Equity is affecting real, lasting change.

The Bristol Myers Squibb Foundation (BMSF) is the founding partner and primary funder of the Winn CDA program. BMSF is engaging its partners and other stakeholders to develop, execute, evaluate, and promote this innovative initiative to increase diversity in clinical trials, tapping into the often overlooked but powerful resource of racially and ethnically diverse physicians or other physicians who have a demonstrated commitment to increasing diversity in clinical trials. This $100 million commitment represents the largest initiative under the Bristol Myers Squibb (BMS) and BMSF 5-year commitment of $300 million to accelerate and expand health equity and diversity and inclusion.

GILEAD SCIENCES, INC.

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

In April 2021, Gilead Sciences joined as a program supporter with a funding commitment of $14 million. Gilead Sciences is a program supporter, committing $14 million to sponsor a total of 40 Winn CDAs and 40 Winn CIPP awards through 2027. The program partners encourage others in the healthcare industry to consider participating as faculty and/or sponsors.

AMGEN

Amgen is a values-based company, deeply rooted in science and innovation to transform new ideas and discoveries into medicines for patients with serious illnesses. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

In January 2023, Amgen joined as a program supporter with a funding commitment of $8 million. Amgen is a program supporter, committing $8 million to sponsor a total of 18 Winn CDAs and 18 Winn CIPP awards through 2027.

VIRGINIA COMMONWEALTH UNIVERSITY

As the implementation partner for Winn CDA, Virginia Commonwealth University (VCU) is responsible for many aspects of Winn CDA's design, development, implementation, and management. VCU recruits and secures formal agreements (e.g. Memoranda of understanding and letters of agreement) with the different program participants, including National Advisory Committee members, Winn CDA Scholar Mentors, speakers, lecturers, Winn Clinical Investigator Pathway Program (CIPP) Students and stakeholders. VCU is directly responsible for ongoing program monitoring and routine process evaluation and will oversee the external evaluation process including selection of the evaluation partner. VCU manages these critical stakeholder relationships and facilitates linkages between these groups to ensure participants' commitment to the program.

Virginia Commonwealth University is a major, urban public research university with national and international rankings in sponsored research. Located in downtown Richmond, VCU enrolls nearly 29,000 students in 238 degree and certificate programs in the arts, sciences and humanities. Twenty-three of the programs are unique in Virginia, many of them crossing the disciplines of VCU's 11 schools and three colleges. The VCU Health brand represents the VCU health sciences academic programs, the VCU Massey Cancer Center and the VCU Health System, which comprises VCU Medical Center (the only academic medical center in the region), Community Memorial Hospital, Tappahannock Hospital, Children's Hospital of Richmond at VCU, and MCV Physicians. The clinical enterprise includes a collaboration with Sheltering Arms Institute for physical rehabilitation services. For more, please visit vcu.edu and vcuhealth.org.

AMERICAN ASSOCIATION FOR CANCER RESEARCH

The American Association for Cancer Research (AACR) is the first and largest cancer research organization dedicated to accelerating the conquest of cancer. Through its programs and services, AACR fosters research in cancer and related biomedical science; accelerates the dissemination of new research findings among scientists and others dedicated to the conquest of cancer; promotes science education and training; and advances the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world.

The American Association for Cancer Research (AACR), in collaboration with BMSF and VCU, will host a week-long training, the Robert A. Winn Diversity in Clinical Trials: Design and Implementation of Clinical Trials (DICT) Workshop, that exposes early-stage investigators to the full spectrum of challenges in clinical research—surgery; radiotherapy; immunotherapy; targeted therapy; treatment with conventional and investigational agents and devices; multidisciplinary treatment regimens; multimodality and combination treatments; the integration of biomarkers in clinical trials; and the application of data science, machine learning, and emerging technologies to clinical research and digital health.

OTHER STAKEHOLDERS

NATIONAL ADVISORY COMMITTEE

The Winn Award National Advisory Committee (NAC) was established to provide valuable guidance and direction on program development. Composed of distinguished clinical research experts representing stakeholders across the clinical research landscape, NAC members provide input related to program design and policy, and participate in Scholar recruitment, review, and selection processes; and serve as moderators and contributors to program events.

HEALTH AND HUMAN SERVICES PARTNERS

BMSF and VCU also receive advisory support from partner organizations within the US Department of Health and Human Services (HHS), such as the National Institutes of Health (NIH). The National Cancer Institute, National Center for Advancing Translational Sciences, and other NIH/HHS partners provide valuable insights for the Winn Award program development, serve on review and selection committees, are guest lecturers, and contribute to program events.

WINN CDA SCHOLARS

The goal of the Winn CDA is to develop a new generation of world class clinical investigators dedicated to increasing diversity in clinical trials. We will achieve this goal by providing immersive community-based experiences in clinical trial research over a five-year period to 308 physicians (MD, DO, MD/PhD, DO/PhD) from groups underrepresented in medicine or who have demonstrated their commitment to increasing diversity in clinical research.

Winn CDA Scholars are a distinguished group of physicians selected for this bold new initiative to transform the clinical research landscape. Together we will strengthen partnerships between clinical investigators and communities, increase the diversity of patients enrolled in clinical trials,

and enhance the development of therapeutics for all populations. The Winn CDA will provide Scholars with sponsorship, training, and mentoring to support their development as clinical investigators advancing health equity. Winn CDA Scholars will receive training in investigator-initiated and industry-sponsored clinical trials, and in trauma-informed community outreach and engagement.

WINN CDA MENTORS

Each Winn CDA Scholar will be mentored by a Principal Investigator (PI) at an established clinical trial site and will substantively participate in the PI's active clinical trial. Mentors will engage Scholars in the conduct of existing clinical trials and provide exposure to all aspects of clinical trial administration and implementation. Twenty-five per cent (25%) of the Mentor's focus will be on career, personal, and professional mentoring for the Scholar. The Mentor will provide guidance on career and professional development with a particular focus on challenges, opportunities, and strategies for URiM researchers. Mentor-Scholar interaction requirements include at least four meetings per month, of which three will be related to clinical trial research related activities.

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: CLINICAL INVESTIGATOR PATHWAY PROGRAM (WINN CIPP) STUDENTS

As part of the Winn CDA, Scholars will serve as mentors to URM medical students (MD, DO, MD/PhD, DO/PhD) participating in the Robert A. Winn Diversity in Clinical Trials: Clinical Investigator Pathway Program (CIPP). Winn CIPP is a 6-week intensive and immersive summer service-learning externship designed to expose talented medical students of diverse backgrounds to clinical research in community-based clinical research settings (e.g., community health centers, safety net hospitals, clinical research organization). The goal of the Winn CIPP is to build the pathway of community-oriented clinical trialists of diverse backgrounds who are committed to increasing inclusion, equity, and diversity in the conduct of clinical and translational research. Winn CIPP Students will gain exposure to clinical research and acquire community engagement and leadership

skills. During their 6-week externships, Winn CIPP students will meet at least 4 times with their Winn CDA Scholar mentors to discuss clinical research career pathways.

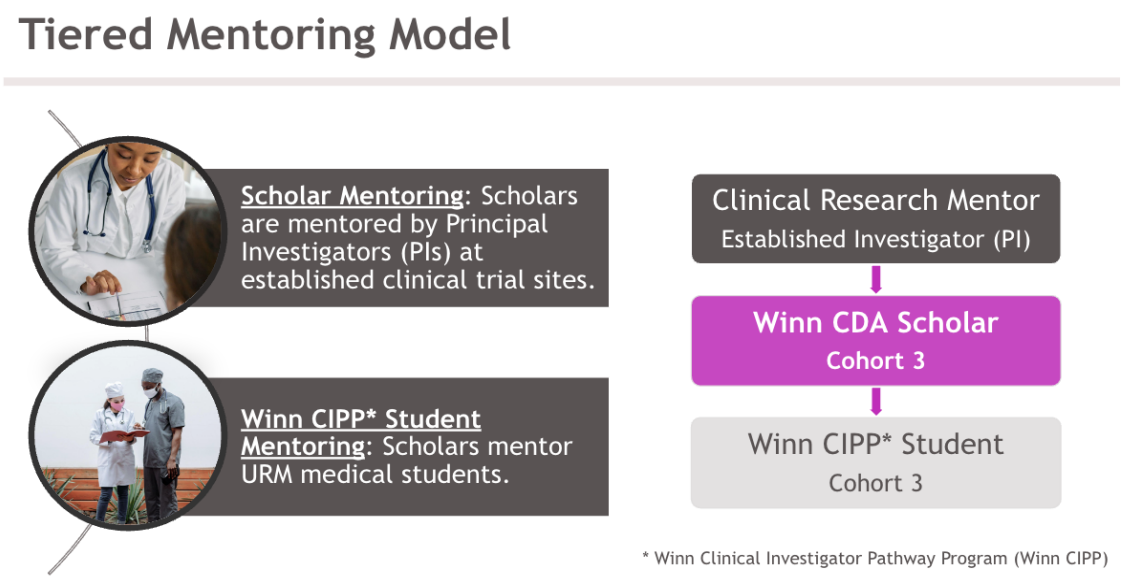
SECTION 2

ABOUT WINN CDA MENTORING

Mentorship is a critical aspect of the Winn CDA, because mentoring can have a critical impact on the success of early-career investigators in navigating challenges and obstacles as they pursue clinical research opportunities—particularly when they are from groups underrepresented in medicine. But, generally, scientific mentoring is one of the most important obligations of senior scientists and has several important goals:

- Teaching an approach and methodology for scientific investigation
- Developing a sense of what questions are able to be answered and have significant answers
- Transmitting a history of ideas in a discipline
- Encouraging development of the ability to evaluate critically the quality of one's own and others' research
- Providing an ethical framework for the conduct of research
- Enhancing the development of oral and written communication skills
- Facilitating entrance into the research community in the discipline

In fact, to amplify the importance of mentoring in the career development of clinical researchers, the Winn CDA incorporates a tiered mentoring model. Even as Winn CDA Scholars are mentored by senior colleagues in the two-year program, they also gain mentoring experience by serving as mentors to medical students interested in clinical research. Each summer, they will provide career development mentoring to medical students from diverse bac in the 6-week Winn Clinical Research Pathway Program (CIPP).



WINN CDA MENTORING GUIDELINES

The goals of mentoring in the Winn CDA are:

1. To produce Winn CDA Scholars who possess the knowledge, skills, and competencies of world class clinical trial researchers.
2. To produce a new generation of Community-Oriented Clinical Trialists who possess the knowledge, skills and competencies to build trust with patient populations underrepresented in medicine and to thereby increase their engagement in clinical trials.

Winn CDA Mentors will achieve these goals by providing career development support and guidance to Winn CDA Scholars as the Scholars assist you in implementing your active clinical trials.

Specifically…

WINN CDA MENTOR ROLE

Provides clinical research experience, support, and guidance to their Winn CDA Scholar for shaping their career in community-oriented clinical research, including:

- Supporting the creation and ongoing development of the Scholar's Individual Professional Development Plan (IPDP)
- Modeling a sustainable career path
- Offering guidance regarding incorporating personal experience into professional life
- Identifying opportunities that may further professional achievement, or barriers that may hinder it, particularly for underrepresented groups

RESPONSIBILITIES OF WINN CDA MENTOR

During the Winn CDA Scholar's two-year program:

- Schedule and complete a minimum of four interactions per month with assigned Winn CDA Scholar, three of which shall be in-person meetings related to clinical trial research activities.
- Commit an estimated 8 hrs/wk to Scholar mentoring:
    - 75% (6 hrs/wk) to clinical trial research mentoring, that engages the Scholar in the conduct of an existing clinical trial and provides exposure to all aspects of CT administration and implementation
    - 25% (2 hrs/wk) to career (e.g., personal and professional) development mentoring, with a particular focus on challenges, opportunities, and strategies for researchers underrepresented in medicine.
- Support the creation and ongoing development of the Scholar's Individual Professional Development Plan (IPDP).

In addition, Winn CDA Mentors participate in Winn CDA program monitoring and evaluation activities, including completion of surveys and interviews with program evaluators.

Mentorship Model – Mentor Time Allocation

Activity	Hrs/ Wk	Hrs/Yr	Days/ Mo	Days/ Yr	Total Days/Yr (2 Yrs)
Clinical Trial Mentoring (75%)	≈6	≈312	≈3.25	≈39	78
Personal/Professional/Career Development Mentoring (25%)	≈2	≈104	≈0.75	≈9	18
Total	8	416	4	48	96

NOTE: Based on 8 hrs/day & 52 wks/yr

THE MENTOR/MENTEE RELATIONSHIP

Within the first month of the program, the Mentor and Scholar will develop and submit a Mentoring Agreement (Appendix I) which will include an outline of expectations (e.g., responsibilities and activities) and interactions (e.g., meeting frequency and types) of the mentoring relationship. The Mentoring Agreement will be reviewed and updated on a quarterly basis.

Within the first month the Mentor will also review the Scholar's Individual Professional Development Plan (Appendix II), which is both their training and career development roadmap for the two-year program and beyond, and their monitoring and outcomes tracking record.

In your first four meetings, please be sure to discuss:

- Your mutual goals for mentoring
- The Winn CDA Mentoring Agreement
- Your personal and professional experiences
- The Scholar's long- and short-term goals for their respective clinical research career paths
- Issues related to underrepresentation in clinical trials
- Career guidance aligned with Scholar's Individual Professional Development Plan (IPDP)

SCHOLAR'S INDIVIDUAL PROFESSIONAL DEVELOPMENT PLAN (IPDP)

Mentors will support their Scholars in developing Individual Professional Development Plans (IPDPs), informed by skills assessments, that will guide the training activities Scholars pursue during the 2-year Winn CDA program. The IPDP will address both clinical research skills (e.g., statistical analysis, biostatistics, etc.) and career/professional development skills (e.g., public speaking, technical report writing, project management, networking). It will thus serve as both the Scholar's training and career development roadmap and their monitoring and outcomes tracking record.

Scholars should begin developing their IPDPs as soon as they begin their program year and review them with mentors during the first or second meeting. VCU will schedule virtual IPDP meetings with

each Scholar within two months of the program start. The finalized plan will be signed by the Scholar, Mentor, and Winn CDA Director within three months of the Scholar's program start. The IPDP will be reviewed biannually and revised as needed.

IPDP TIMELINE

- Scholar creates IPDP: Nov 2023
- Mentor reviews Scholar's IPDP: Nov – Dec 2023 (first or second meeting)
- Winn CDA holds IPDP meetings with each Scholar: Jan-Feb 2024
- Scholar, Mentor, and Winn CDA Director sign finalized IPDP: Feb-Mar 2024
- IPDP Review Status Sessions: Jul & Dec 2024, May & Oct 2025

Biannual reviews of the Scholar's progress toward achieving the goals of the IPDP are helpful for both the Mentor and the Scholar to ensure that potential barriers to success are addressed in a timely manner and that the Scholar's career goals are indeed achieved.

SECTION 3

PROGRAM MONITORING AND EVALUATION

Winn CDA Mentors will participate in program monitoring and evaluation activities, as these are critical to understanding how the Winn CDA is working and to measuring the program's overall success. Mixed methods will be used to elicit feedback from program stakeholders to monitor and assess different aspects of the program. Routine collection of program data will be used to improve processes and administration and to identify best practices and incorporate lessons learned. Mentors will participate in various evaluation activities including completion of survey questionnaires and individual meetings/interviews.

An external evaluator will be contracted to perform formal program evaluations at the end of cohorts 1, 3, and 5. A final impact evaluation will be conducted 2-years after the final cohort ends in 2029. Mentors will participate in Scholars' program award period.

SECTION 4

MENTOR HONORARIUM

Each Winn CDA Primary Mentor will be paid an honorarium of $4,800 per year. At the beginning of each program year, Winn CDA will send each Mentor a Memorandum of Understanding (MOU) detailing the roles and responsibilities of the Mentor in supporting the Winn CDA Scholar and in participating in Winn CDA program evaluation activities.

Along with the MOU, Winn CDA will send documents required for disbursement of honoraria. Honoraria will be disbursed annually, at the end of each program year, and are conditioned on the fulfillment of responsibilities specified in the Mentorship Memorandum of Understanding.

Mentors' fulfillment of requirements will be monitored twice annually through Mentor Status Reports (online surveys), one of which will include an Annual Mentorship Assessment. Virtual follow-up meetings with individual Mentors will be scheduled as appropriate.

SECTION 5

MENTOR SUPPORT

Winn CDA will provide both individual and group mentoring support throughout the 2-year Winn CDA. At the beginning of the program, Mentors will participate in a virtual orientation that provides an overview of the Winn CDA and of Mentors' roles and responsibilities. Throughout the program, Winn CDA will share resources on mentoring and invite Mentors to periodic Winn CDA Mentor meetings where they may share experiences, concerns, challenges, and best practices.

SECTION 6

PROGRAM STAFF CONTACTS

Questions or concerns related to the implementation of the program should be directed to:

Winn CDA program
winncda@vcu.edu

Ali Gemma, MPH
Director, Career Development Award
gemmaa@vcu.edu
804-628-8883

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Senior Program Coordinator, Career Development Award
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804-628-8882

Joy L. Jones, PhD
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804-628-8878

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Executive Assistant to the Executive Director, Winn Awards
broadrn@vcu.edu
804-628-8884

SECTION 7

APPENDICES

APPENDIX A

WINN CDA SCHOLAR-MENTOR MENTORING AGREEMENT

APPENDIX B

WINN CDA INDIVIDUAL PROFESSIONAL DEVELOPMENT PLAN

APPENDIX C

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: DESIGN AND IMPLEMENTATION OF CLINICAL TRIALS (DICT) WORKSHOP IN PARTNERSHIP WITH AMERICAN ASSOCIATION FOR CANCER RESEARCH (WINN DICT WORKSHOP)

APPENDIX D

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: COMMUNITY-ORIENTED CLINICAL TRIALIST TRAINING (WINN COCT) SYLLABUS

APPENDIX E

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: COMMUNITY-ORIENTED CLINICAL TRIALIST TRAINING (WINN COCT) SELF-ASSESSMENT

SECTION 8

THANKS TO

Winn Awards Partners and Collaborators

FUNDING PARTNERS

Bristol Myers Squibb Foundation

GILEAD

AMGEN

IMPLEMENTATION PARTNERS

VCU

AACR American Association for Cancer Research

FINDING CURES TOGETHER

APPENDIX A:
WINN CDA SCHOLAR-MENTOR MENTORING AGREEMENT

The Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA)

Mentoring Agreement

The Winn CDA Scholar and Mentor should complete this Mentoring Agreement during the first mentoring meeting. The agreement serves as a reminder that the Scholar and Mentor are voluntarily entering into a partnership.

This agreement is made between_____ (Scholar) and _____(Mentor). We are voluntarily entering into this mentoring relationship, the purpose of which is to support the Scholar's career development. To ensure a productive and rewarding experience for both parties, we agree to the following terms.

Expectations

The Mentor shall:

- Provide clinical research experience, support, and guidance to the Scholar for shaping their career in community-oriented clinical research
- Support the creation and ongoing development of the Scholar's Individual Professional Development Plan (IPDP)
- Model a sustainable career path
- Offer guidance regarding incorporating personal experience into professional life
- Identify opportunities that may further the Scholar's professional achievement or barriers that may hinder it

The Scholar shall:

- Participate actively and responsibly in the Mentor's clinical research
- Act promptly to develop the Individual Professional Development Plan (IPDP)
- Maintain regular meetings and communication with the Mentor
- Proactively pursue Mentor-recommended opportunities and experiences to enhance learning
- Review and revise the IPDP as they work toward identified goals

Meetings

The Mentor and Scholar shall schedule and complete a recommended minimum of four interactions per month, three of which shall be related to clinical trial research activities. Both the Mentor and Scholar shall commit an estimated 8 hours per week to the mentoring relationship covering:

- Clinical trial research mentoring, that engages the Scholar in the conduct of an existing clinical trial and provides exposure to all aspects of CT administration and implementation

- Career (e.g., personal and professional) development mentoring, with a particular focus on challenges, opportunities, and strategies for researchers underrepresented in medicine.

  The Scholar and Mentor shall meet at mutually agreed upon times and places. Meeting times, once agreed to, should not be canceled unless it is unavoidable. Meetings that are canceled shall be rescheduled.

Duration of Relationship

The Mentor and Scholar intend to maintain the mentoring relationship for two years (November 2023 through October 2025). However, either party has the option of discontinuing the relationship, provided the terminating party first notifies the Winn CDA program director.

Confidentiality

All information shared between the Scholar and Mentor shall be confidential.

Acceptance

By signing this agreement, we indicate our acceptance of the terms above. We understand that circumstances may change in the course of two years. We further agree that we shall review and update this agreement on a quarterly basis. If at any time during the duration of the mentoring agreement one party does not feel able or willing, or feels the other is not able or willing, to fulfill the terms of the agreement, they shall notify the Winn CDA program director.

Name of Winn CDA Scholar: _____

Scholar's Signature:_____Date: _____

Name of Winn CDA Mentor: _____

Mentor's Signature:_____Date: _____

APPENDIX B:
WINN CDA INDIVIDUAL PROFESSIONAL DEVELOPMENT PLAN

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA)

Individual Professional Development Plan

The Winn CDA Individual Professional Development Plan (IPDP) is designed to inform and guide your training and other career development activities during your two-year journey toward becoming a community-oriented clinical trialist. The plan will address both your clinical research skills (e.g., statistical analysis, biostatistics) and your career/professional development skills (e.g., public speaking, technical report writing, project management), and will serve as both your career development roadmap and your monitoring and outcomes tracking record.

Begin writing your IPDP immediately, as you will review it with your clinical research mentor during your first or second meeting (November-December). Winn CDA staff will schedule virtual IPDP meetings with Winn CDA Scholars in January and February to review your plans. You, your mentor, and a Winn CDA Director will sign your finalized IPDP by March 31, 2024. We will review your IPDP biannually; you may revise it as needed.

SECTION 1: SCHOLAR AND MENTOR INFORMATION

SCHOLAR INFORMATION

Name:	
Title:	
Institution:	
City and State:	
Preferred Email Address:	
Preferred Phone:	

MENTOR INFORMATION

Name:	
Title:	
Institution:	
City and State:	
Preferred Email Address:	
Preferred Phone:	

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
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SECTION 2: CAREER GOALS

I. LONG TERM CAREER STATEMENT (1 - 2 paragraphs)

II. SHORT TERM CAREER GOALS (3 - 4 sentences each)

a. One-Year Goals:

b. Two-Year Goals:

c. Five-Year Goals:

III. CURRENT RESEARCH TRAJECTORY (Significance, Innovation, Approach, and Broader Impacts of existing projects)

IV. FUTURE RESEARCH TRAJECTORY (Significance, Innovation, Approach, Broader Impacts of projects you hope to pursue in the future)

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

SECTION 3: TRAINING & CAREER DEVELOPMENT PLAN

Begin your training and career development process by specifying the knowledge, skills, and competencies you must now acquire to achieve the career goals you have defined above—e.g., stronger knowledge of biostatistics, grant writing skills, increased cultural competency). For each need, specify means of fulfilling it, and indicate the date by which you plan to achieve that knowledge, skill, or competency. This is a living document—you can revise it at any time.

NEEDS **[Knowledge, Skills, and Competencies]**	**ACQUISITION PLAN** **[Methods and Timelines]**

Last update: _____

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
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SECTION 4: CAREER DEVELOPMENT PLAN – 2023-2025

I. CLINICAL RESEARCH

Clinical Research Experiences		
Experience	Proposed Date	Completed Date
Clinical Investigator Training		
Training Event	Proposed Date	Completed Date

II. COMMUNITY ENGAGEMENT

Community Engagement Experiences		
Experience	Proposed Date	Completed Date
Community Engagement Training		
Training Event	Proposed Date	Completed Date

III. GRANT SUBMISSIONS AND FUNDING OPPORTUNITIES

Grant Writing/Proposal Development Workshops		
Name, Type, and Focus	Proposed Date	Completed Date
Concept Paper and Mock Grant Review		
Meeting Name	Proposed Date	Completed Date
Submission of Awards (Internal, External)		
Topic, Type, Internal or External	Proposed Date	Completed Date

Grant Development Activities		
Activities	Proposed Date	Completed Date
Resubmission (Internal, External)		
Topic, Type, Internal or External	Proposed Date	Completed Date

IV. PRESENTATIONS AND PUBLICATIONS

Presentations		
Meeting Name	Proposed Date	Completed Date
Writing Workshops and Retreats		
Workshop or Retreat	Proposed Date	Completed Date
Publications		
Publication Title and Publication Outlet	Proposed Date	Completed Date

V. PROFESSIONAL CONTACTS AND COMMUNITY

Collaboration Opportunities with Colleagues (Internal and External)		
Type, Name, and Venue	Proposed Date	Completed Date
Membership, Service, Organizing, and Attending Regional and National Meetings/Associations		
Type and Venue	Proposed Date	Completed Date
Other Networking Activities		
Type, Name, and Venue	Proposed Date	Completed Date

VI. MENTORSHIP AND SERVICE

Mentorship by Senior Colleagues		
Proposed Mentor	Proposed Date	Completed Date
Mentoring of Other Colleagues and Students		
Proposed Mentee	Proposed Date	Completed Date
Professional Service Activities		
Type, Name, and Venue	Proposed Date	Completed Date

VII. RECOGNITION

Awards and Honors		
Award/Honor Type	Proposed Date	Completed Date

This Individual Professional Development Plan has been reviewed carefully and is agreed to by:

Scholar: _____

Scholar's Signature: _____ Date: _____

Mentor: _____

Mentor's Signature: _____ Date: _____

Winn CDA Director: _____

Winn CDA Director's Signature: _____ Date: _____

APPENDIX A: CURRICULUM VITAE

(Attach formal CV for review)

APPENDIX B: IPDP UPDATE#1 (due November 2024)

The goal of these updates is to outline and map your progress, challenges, successes and continued or changed trajectory as a result of your participation in the Winn CDA program and your mentorship support. For any of your original goals previously outlined, please enter the completed date in the corresponding row in the previously completed sections. Please include detailed updates for each section below. **If you have no changes to a particular section, please leave that section blank.**

SECTION 2: CAREER GOALS

I. LONG TERM CAREER STATEMENT
(If any changes to your long-term career statement, please detail below.)

II. SHORT TERM CAREER GOALS
(If any changes to your short-term career goals, please detail below.)

a. One-Year Goals:

b. Two-Year Goals:

c. Five-Year Goals:

III. CURRENT RESEARCH TRAJECTORY
(If any changes to your current research trajectory, please detail below.)

IV. FUTURE RESEARCH TRAJECTORY
(If any changes to your future research trajectory, please detail below.)

SECTION 3: TRAINING & CAREER DEVELOPMENT PLAN

(If any changes to your training and career development plan, please detail below.)

NEEDS [Knowledge, Skills, and Competencies]	ACQUISITION PLAN [Methods and Timelines]

SECTION 4: CAREER DEVELOPMENT PLAN – 2023-2025

(If any changes to your career development plan, please detail below.)

I. CLINICAL RESEARCH *(If any changes to your clinical research plan, please detail below.)*

Clinical Research Experiences		
Experience	Proposed Date	Completed Date
Clinical Investigator Training		
Training Event	Proposed Date	Completed Date

II. COMMUNITY ENGAGEMENT *(If any changes to your community engagement plan, please detail below.)*

Community Engagement Experiences		
Experience	Proposed Date	Completed Date
Community Engagement Training		
Training Event	Proposed Date	Completed Date

III. GRANT SUBMISSIONS AND FUNDING OPPORTUNITIES

(If any changes to your grant submissions and funding opportunities plan, please detail below.)

Grant Writing/Proposal Development Workshops		
Name, Type, and Focus	Proposed Date	Completed Date
Concept Paper and Mock Grant Review		
Meeting Name	Proposed Date	Completed Date
Submission of Awards (Internal, External)		
Topic, Type, Internal or External	Proposed Date	Completed Date

Grant Development Activities		
Activities	Proposed Date	Completed Date
Resubmission (Internal, External)		
Topic, Type, Internal or External	Proposed Date	Completed Date

IV. PRESENTATIONS AND PUBLICATIONS *(If any changes to your presentations and publications, please detail below.)*

Presentations		
Meeting Name	Proposed Date	Completed Date
Writing Workshops and Retreats		
Workshop or Retreat	Proposed Date	Completed Date
Publications		
Publication Title and Publication Outlet	Proposed Date	Completed Date

V. PROFESSIONAL CONTACTS AND COMMUNITY *(If any changes to your professional contacts and community, please detail below.)*

Collaboration Opportunities with Colleagues (Internal and External)		
Type, Name, and Venue	Proposed Date	Completed Date
Membership, Service, Organizing, and Attending Regional and National Meetings/Associations		
Type and Venue	Proposed Date	Completed Date
Other Networking Activities		
Type, Name, and Venue	Proposed Date	Completed Date

VI. MENTORSHIP AND SERVICE *(If any changes to your mentorship and service plan, please detail below.)*

Mentorship by Senior Colleagues		
Proposed Mentor	Proposed Date	Completed Date
Mentoring of Other Colleagues and Students		
Proposed Mentee	Proposed Date	Completed Date
Professional Service Activities		

Type, Name, and Venue	Proposed Date	Completed Date

VII. RECOGNITION *(If any changes to your recognitions, please detail below.)*

Awards and Honors		
Award/Honor Type	Proposed Date	Completed Date

This updated Individual Professional Development Plan has been reviewed carefully and is agreed to by:

Scholar: _____

Scholar's Signature: _____ Date: _____

Mentor: _____

Mentor's Signature: _____ Date: _____

Winn CDA Director: _____

Winn CDA Director's Signature: _____ Date: _____

APPENDIX C: IPDP UPDATE #2 (due October 2025)

The goal of these updates is to outline and map your progress, challenges, successes and continued or changed trajectory as a result of your participation in the Winn CDA program and your mentorship support. For any of your original goals previously outlined, please enter the completed date in the corresponding row in the previously completed sections. Please include detailed updates for each section below. **If you have no changes to a particular section, please leave that section blank.**

SECTION 2: CAREER GOALS

I. LONG TERM CAREER STATEMENT
(If any changes to your long-term career statement, please detail below.)

II. SHORT TERM CAREER GOALS
(If any changes to your short-term career goals, please detail below.)

a. One-Year Goals:

b. Two-Year Goals:

c. Five-Year Goals:

III. CURRENT RESEARCH TRAJECTORY
(If any changes to your current research trajectory, please detail below.)

IV. FUTURE RESEARCH TRAJECTORY
(If any changes to your future research trajectory, please detail below.)

SECTION 3: TRAINING & CAREER DEVELOPMENT PLAN

(If any changes to your training and career development plan, please detail below.)

NEEDS [Knowledge, Skills, and Competencies]	ACQUISITION PLAN [Methods and Timelines]

SECTION 4: CAREER DEVELOPMENT PLAN – 2023-2025

(If any changes to your career development plan, please detail below.)

VIII. CLINICAL RESEARCH *(If any changes to your clinical research plan, please detail below.)*

Clinical Research Experiences		
Experience	Proposed Date	Completed Date
Clinical Investigator Training		
Training Event	Proposed Date	Completed Date

IX. COMMUNITY ENGAGEMENT *(If any changes to your community engagement plan, please detail below.)*

Community Engagement Experiences		
Experience	Proposed Date	Completed Date
Community Engagement Training		
Training Event	Proposed Date	Completed Date

X. GRANT SUBMISSIONS AND FUNDING OPPORTUNITIES

(If any changes to your grant submissions and funding opportunities plan, please detail below.)

Grant Writing/Proposal Development Workshops		
Name, Type, and Focus	Proposed Date	Completed Date
Concept Paper and Mock Grant Review		
Meeting Name	Proposed Date	Completed Date
Submission of Awards (Internal, External)		
Topic, Type, Internal or External	Proposed Date	Completed Date

Grant Development Activities		
Activities	Proposed Date	Completed Date
Resubmission (Internal, External)		
Topic, Type, Internal or External	Proposed Date	Completed Date

XI. PRESENTATIONS AND PUBLICATIONS *(If any changes to your presentations and publications, please detail below.)*

Presentations		
Meeting Name	Proposed Date	Completed Date
Writing Workshops and Retreats		
Workshop or Retreat	Proposed Date	Completed Date
Publications		
Publication Title and Publication Outlet	Proposed Date	Completed Date

XII. PROFESSIONAL CONTACTS AND COMMUNITY *(If any changes to your professional contacts and community, please detail below.)*

Collaboration Opportunities with Colleagues (Internal and External)		
Type, Name, and Venue	Proposed Date	Completed Date
Membership, Service, Organizing, and Attending Regional and National Meetings/Associations		
Type and Venue	Proposed Date	Completed Date
Other Networking Activities		
Type, Name, and Venue	Proposed Date	Completed Date

XIII. MENTORSHIP AND SERVICE *(If any changes to your mentorship and service plan, please detail below.)*

Mentorship by Senior Colleagues		
Proposed Mentor	Proposed Date	Completed Date
Mentoring of Other Colleagues and Students		
Proposed Mentee	Proposed Date	Completed Date
Professional Service Activities		

Type, Name, and Venue	Proposed Date	Completed Date

XIV. RECOGNITION *(If any changes to your recognitions, please detail below.)*

Awards and Honors		
Award/Honor Type	Proposed Date	Completed Date

This updated Individual Professional Development Plan has been reviewed carefully and is agreed to by:

Scholar: _____

Scholar's Signature: _____ Date: _____

Mentor: _____

Mentor's Signature: _____ Date: _____

Winn CDA Director: _____

Winn CDA Director's Signature: _____ Date: _____

APPENDIX C:
WINN DICT WORKSHOP

Robert A. Winn Diversity in Clinical Trials:

Design and Implementation of Clinical Trials Workshop

in partnership with the American Association for Cancer Research

November 15-19, 2023 | Hilton La Jolla Torrey Pines | La Jolla, CA

WEDNESDAY, NOVEMBER 15

Arrival / Registration

12:00 pm-5:00 pm

Faculty Meeting 1

3:30 pm-4:30 pm

Welcome and Opening Session

5:00 pm-7:00 pm

5:00-5:20	**Welcome and Workshop Overview**
5:20-5:30	**Introduction of Keynote Speaker**
5:30-6:00	**Keynote Address**
6:00-6:15	**Keynote Q&A**
6:15-7:00	**Panel Discussion on Community Outreach and Engagement**

Break

7:00 pm-7:30 pm

Opening Reception

7:30 pm-9:30 pm

THURSDAY, NOVEMBER 16

Breakfast

7:00 am-8:00 am

Education Session/Core Curriculum 1

8:00 am-9:40 am

Clinical Trial Design: Asking Important Questions That Impact Our Patients

8:00-8:20	**FDA Perspective**
8:20-8:40	**Autoimmune Diseases**
8:40-9:00	**Cardiovascular Diseases**
9:00-9:20	**Oncology / Hematology**
9:20-9:40	**Q&A / Discussion**

Break
9:40 am-10:00 am

Education Session/Core Curriculum 2
10:00 am-12:00 pm

Clinical Trial Design Questions

10:00-10:20	**Answering Important Questions: From Hypothesis to Analysis**
10:20-11:00	**Phase I Trial Questions, Objectives, and Designs**
11:00-11:40	**Phase II Trial Questions, Objectives, and Designs**
11:40-12:00	**Q&A / Discussion**

Lunch
12:00 pm-1:15 pm

Education Session/Core Curriculum 3
1:15 pm-2:15 pm

Biomarkers

1:15-1:35	**Biomarkers**
1:35-1:55	**Design Considerations for Biomarker Driven Trials in Oncology**
1:55-2:15	**Q&A / Discussion**

Break
2:15 pm-2:30 pm

Concurrent Sessions 1-2
(optional sessions running concurrently, offered twice)
2:30 pm-3:30 pm

Pragmatic Trials
Symptom Control Trials: Recommendations for Success

Break
3:30 pm-3:45 pm

Clinical Trial Development / Case Discussion Session 1
3:45 pm-5:45 pm

Dinner Available
6:00 pm-7:15 pm

Faculty Mentoring Sessions 1

(30-minute appointments, sign-up required)

6:30 pm-8:30 pm

FRIDAY, NOVEMBER 17

Breakfast

7:00 am-8:00 am

Faculty Meeting 2

7:00 am-7:55 am

Education Session/Core Curriculum 4

8:00 am-9:00 am

Special Considerations in the Design of Immunotherapy Studies

8:00-8:20	**Special Considerations in the Design of Immunotherapy Studies: Autoimmune Diseases**
8:20-8:40	**Special Considerations in the Design of Immunotherapy Studies: Oncology / Hematology**
8:40-9:00	**Q&A / Discussion**

Break

9:00 am-9:10 am

Education Session/Core Curriculum 5

9:10 am-10:40 am

Ethics and Artificial Intelligence in Clinical Trials

9:10-9:30	**Data Science, Artificial Intelligence, and Machine Learning**
9:30-9:50	**Clinical Trial Ethics and Informed Consent**
9:50-10:10	**You're in Charge: Investigator Responsibilities (including COI)**
10:10-10:40	**Q&A / Discussion**

Break

10:40 am-10:50 am

Education Session/Core Curriculum 6

10:50 am-11:30 am

Team Science

10:50-11:30	**Panel Discussion on Team Science**

Break
11:30 am-11:45 am

Concurrent Sessions 3-4
(optional sessions running concurrently, offered twice)
11:45 am-12:45 pm

Pragmatic Trials
Symptom Control Trials: Recommendations for Success

Cohort 3 Group Photo
12:45 pm-1:00 pm

Lunch
1:00 pm-1:45 pm

Clinical Trial Development / Case Discussion Session 2
1:45 pm-3:45 pm

Break
3:45 pm-4:00 pm

Panel Discussion on Health Disparities
4:00 pm-5:15 pm

Group Photo
5:15 pm-5:30 pm

Winn CDA Networking Reception 1
6:00 pm-8:00 pm

SATURDAY, NOVEMBER 18

Breakfast
7:00 am-8:00 am

Education Session/Core Curriculum 7

8:00 am-9:00 am

Regulatory Issues to Consider When Initiating Your Trial

8:00-9:00 **Panel Discussion: Regulatory Issues to Consider When Initiating Your Trial**

Break

9:00 am-9:15 am

Concurrent Sessions 5-6

(optional sessions running concurrently, offered twice)

9:15 am-10:15 am

Addressing Accrual Barriers to Clinical Trial Enrollment of At-risk and Underserved Populations
Statistical Considerations

Break

10:15 am-10:30 am

Clinical Trial Development / Case Discussion Session 3

10:30 am-12:30 pm

Lunch

12:30 pm-1:30 pm

Education Session/Core Curriculum 8

1:30 pm-3:00 pm

Combination Trials and the Patient's Perspective

1:30-2:00 **Combination Trials**
2:00-2:30 **Patient-Reported Outcomes**
2:30-3:00 **Q&A / Discussion**

Break

3:00 pm-3:20 pm

Education Session/Core Curriculum 9

3:20 pm-4:00 pm

Mentoring Why, When, Who, and How

3:20-4:00 **Panel Discussion: Mentoring Why, When, Who, and How**

Break
4:00 pm-4:15 pm

Faculty Mentoring Sessions 2
(30-minute appointments, signups required)
4:15 pm-6:15 pm

Winn CDA Networking Reception 2
6:30 pm-7:30 pm

Cohort 1 Graduation Seated Dinner
7:30 pm-9:30 pm

SUNDAY, NOVEMBER 19

Breakfast
7:00 am-8:00 am

Education Session/Core Curriculum 10
8:00 am-9:50 am

Community Engagement and Impact

8:00-8:20	**Decentralized Clinical Trials**
8:20-8:40	**Inclusivity in Clinical Trials**
8:40-9:00	**Community Outreach/Engagement**
9:00-9:20	**Practical and Idealistic Approaches to Supporting Informed Decisions about Trial Accrual to Achieve Representation**
9:20-9:50	**Q&A / Discussion**

Break
9:50 am-10:00 am

Clinical Trial Development / Case Discussion Session 4
10:00 am-12:00 pm

Lunch Available
12:00 pm-1:30 pm

Faculty Meeting 3

12:15 pm-1:15 pm

Concurrent Sessions 7-8

(optional sessions running concurrently, offered twice)

1:30 pm-2:30 pm

Addressing Accrual Barriers to Clinical Trial Enrollment of At-risk and Underserved Populations
Statistical Considerations

Break

2:30 pm-2:40 pm

Scholar Presentations: Groups 1-4

2:40 pm-4:05 pm

(1 from each CTD group, 10 minutes presentations, 10 minutes Q&A)

2:45-2:55	**CTD Group 1 Scholar Presentation**
2:55-3:05	**Discussion / Q&A**
3:05-3:15	**CTD Group 2 Scholar Presentation**
3:15-3:25	**Discussion / Q&A**
3:25-3:35	**CTD Group 3 Scholar Presentation**
3:35-3:45	**Discussion / Q&A**
3:45-3:55	**CTD Group 4 Scholar Presentation**
3:55-4:05	**Discussion / Q&A**

Break

4:05 pm-4:20 pm

Scholar Presentations: Groups 5-8

4:20 pm-5:40 pm

4:20-4:30	**CTD Group 5 Scholar Presentation**
4:30-4:40	**Discussion / Q&A**
4:40-4:50	**CTD Group 6 Scholar Presentation**
4:50-5:00	**Discussion / Q&A**
5:00-5:10	**CTD Group 7 Scholar Presentation**
5:10-5:20	**Discussion / Q&A**
5:20-5:30	**CTD Group 8 Scholar Presentation**
5:30-5:40	**Discussion / Q&A**

Closing Reception / Dinner

7:30 pm-10:30 pm

MONDAY, NOVEMBER 20

Breakfast and Departure

6:00 am-9:00 am

APPENDIX D:
WINN COCT SYLLABUS

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA)
Community-Oriented Clinical Trialist (COCT) Training

Introduction

The Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA) is developing a new generation of community-oriented clinical trialists committed to increasing the diversity and inclusion of patients enrolled in clinical trials and to enhancing the development of new therapeutics effective in all populations. The program facilitates an approach to clinical and translational research that is community-informed, community-designed, and community-conducted. We provide emerging investigators the resources, tools, and support they need to conduct clinical trials worthy of the trust of our communities.

The two-year **Robert A. Winn Diversity in Clinical Trials: Community-oriented Clinical Trialist (COCT) Training** curriculum equips scholars with the knowledge, skills, and competencies to engage effectively with communities and foster active community participation in clinical and translational research. It features comprehensive training in clinical research design and implementation, community engagement methods and strategies, and skills building to become independent clinical trialists.

Outcomes

Over the course of the two-year Winn COCT Training, scholars will develop and conduct clinical protocols and present them at the **2025 Winn CDA Annual Convening**

Learning Objectives

The Winn COCT Training sequence increases Scholars' knowledge of:

- Basic biostatistical and epidemiologic methods involved in conducting clinical research
- Principles and issues involved in designing, managing, and monitoring patient-oriented research
- Good protocol design
- Good clinical practices (GCPs) related to ethical, legal, and regulatory issues to protect human subjects' safety, rights and welfare in clinical research
- Good clinical practices (GCPs) for ensuring clinical trial validity
- Infrastructure required to perform clinical research, and steps involved in developing and funding research studies

- Social and political determinants of health and their impact on health outcomes among populations underrepresented in clinical research
- Practices for identifying and evaluating catchment area needs
- Effective, community engagement and partnership building practices

Curriculum Requirements

The COCT curriculum has five main components:

1. Scholars Forum (Year 1: Weekly, Year 2: Bi-weekly, 2-3 hours per session)
2. Winn CDA Annual Convening
3. Community Engagement
4. Individual Professional Development Plan
5. Capstone Project

- **Scholars Forum:** Scholars meet with faculty weekly in Year 1; bi-weekly in Year 2 via Zoom for seminars, professional skills workshops, and roundtable discussions with guest speakers. The Scholars Forum will be held on the designated Thursdays at the following times: 12:00 pm-3:00 pm ET/ 11:00 am-2:00 pm CT/ 9:00 am-12:00 pm PT. Scholars are required to attend as live virtual participants via Zoom in a minimum of 80% of the forum sessions (i.e., 34 of 42 for Year 1 and 21 of 26 for Year 2). Live virtual participation for a minimum of 2 hours is required for attendance to be recognized. Scholars are also required to submit a post-webinar survey.
- **Winn Career Development Award (Winn CDA) Annual Convening:** A two-day event to develop the Winn CDA Community of Practice and Network. This annual event is designed to bring together key program stakeholders (e.g., Scholars, National Advisory Committee, program partners and collaborators, etc.) to inspire, amplify, educate and celebrate. The agenda will include sessions addressing Diversity in Clinical Trial Research, skills development, and Scholar presentations. The convening will provide Scholars the opportunity to network with each other and a range of program stakeholders, leaders in clinical trial research, and local Winn CDA alumni.

- **Community Engagement:** Scholars will be given assignments to practice community engagement and partnership building skills and to deepen their knowledge of their catchment areas by hosting focus groups, key informant interviews, and listening sessions, and by attending other meetings within their local communities.

- **Individual Professional Development Plan:** Each Scholar will develop an Individual Professional Development Plan (IPDP) informed by a skills self-assessment that will guide the training activities Scholars pursue during the two-year Winn CDA program. The IPDP will address both clinical research skills (e.g.,

statistical analysis, biostatistics, etc.) and career/professional development skills (e.g., public speaking, technical report writing, project management, networking, etc.). The Winn CDA staff will schedule virtual IPDP meetings with each Scholar within two-months of the program start. In addition, the Scholar will review the IPDP with their clinical research mentor during the first or second meeting. The finalized plan will be signed by the Scholar, Mentor, and Winn CDA Director within three-months of the Scholar's program start. The IPDP will be reviewed biannually and revised as needed. The IPDP will serve both as the training and career development roadmap and the individual Scholar monitoring and outcomes tracking record.

- **Capstone Project:** Each Scholar will design and develop a mentored research protocol proposed during the two-year program period. The capstone will focus on major issues in research protocol development, including development of a research question, methodological issues regarding different research designs, and plans for analysis. Each Scholar will present his or her research proposal for open discussion during one of the seminar sessions, and will present their developed protocol at the Year-2 Winn CDA Annual Convening.

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Scholars Forum Overview*

Year 1: Fundamentals of Community-Oriented Clinical Trials		
Investigator Certification Program **8 Sessions** Necessary skills and knowledge for conducting multi-center global clinical trials, based on a sound understanding of Good Clinical Practice (GCP), the legal framework, ethical considerations, and the roles and responsibilities of all parties involved in a trial.	**Foundations of Clinical Trial Design** **10 sessions** Fundamental principles and research concepts involved in the design and conduct of safe and effective clinical trials.	**Community Engagement** **8 sessions** Community outreach, in-reach, and engagement strategies that equip clinical researchers to collaborate effectively with community members to mitigate health disparities imposed or exacerbated by clinical trials.
Interaction Series **4 Sessions** Sessions on how to engage and interact across the multidisciplinary departments and teams.	**Protocol Writing** **2 Sessions** These sessions cover the fundamental components of and strategies for writing effective protocols for the conduct of clinical trials.	**Journal Club** **4 Sessions** Small group discussions of hot topics and the latest scientific and medical literature – each group then presents a summary to the cohort.
Mentoring **2 Sessions** Qualities of effective mentoring, and the role and significance of mentorship in career development, pathway building, and the formation of communities of practice.	**Peer Group Discussions Based on Winn-AACR DICT Workshop CTD Groups** **4 Sessions** Small group discussions and opportunities to workshop their capstone project concepts with fellow scholars. Discuss successes, challenges to increasing patient diversity.	

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
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Year 2: Developing Protocols for Community-Oriented Clinical Trials		
Clinical Trial Design **8 sessions** More advanced training in the design and implementation of clinical research studies.	**Community Engagement** **7 sessions** Further skill development in community outreach, in-reach, and engagement processes.	**Grant Writing Boot Camp** **4 sessions** An intensive grant writing workshop that provides practical guidance for writing NIH R- or K-style grants.
Mock Manuscript/Paper Review **2 sessions** Opportunities for scholars to get formal feedback from experts on manuscripts or papers that they intend to submit for publication.	**Grant Seeking / Funding Research** **1 Session** Learn how to identify opportunities to apply for grants or other research funding.	**Peer Group Project Discussion** **4 Sessions** Continued small group discussions and opportunities to workshop their capstone project concepts with fellow scholars, as they refine for final capstone presentation at Annual Convening.

*NOTE: Curriculum subject to change

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Year 1: Fundamentals of Community-Oriented Clinical Trials

In Year 1, Scholars will learn the basic principles, research concepts, and community engagement strategies that underlie the design and conduct of community-oriented clinical trials. The foundational COCT sequence has eight foci:

(1) Foundations of Clinical Trial Design (10 sessions)
(2) Investigator Certification Program (8 Sessions)
(3) Community Engagement (8 sessions)
(4) Interaction Series (4 Sessions)
(5) Protocol Writing (2 Sessions)
(6) Journal Club (4 Sessions)
(7) Mentoring (2 Sessions)
(8) Peer Group Project Discussions (4 Sessions)

Foundations of Clinical Trial Design
1. Research Methods Introduction to study design and applied quantitative methods in clinical research. Topics include data collection, data management, and analytic techniques.
2. Human Subjects Research Practices and issues pertaining to research involving human subjects. Topics include the historical development of human subject protections, ethical issues, institutional review boards, and current regulations and guidance.
3. Epidemiology Principles and methods of epidemiology. Topics include descriptive epidemiology, risk factors, outbreak detection, demography, and etiologic studies.
4. Barriers to Accrual in Underserved Populations Examination of factors that create barriers to accrual of patients from underserved communities and the impact on the generalizability of clinical trial outcomes. Scholars will explore effective strategies to mitigate barriers.
5. What Is Team Science? Fundamental topics in translational science related to team science. Practical strategies for engaging in team science.
6. Statistical Principles in Clinical Trials The statistical aspects of clinical trials. Topics include types of clinical research, alternative study designs, randomization and stratification, sample size requirements, bias minimization, and interpretation of results.

7. Statistical Methods in Epidemiology Advanced statistical methods used in epidemiological data analysis. Topics include Mantel-Haenszel chi-square, interaction, standardization of rates data, incidence density, and logistics regression.
8. Biostatistics I Introduction to probability and statistics, specifically for analyzing medical data. Topics include descriptive statistics, hypothesis testing, regression analysis, contingency tables, nonparametric tests, and life tables.
9. Biostatistics II Further discussion of probability and statistics in medical data analysis. Topics include design of factorial experiments, analysis of variance and variance components, multiple linear regression, and life tables.
10. Research Ethics Introduction to principles and practicalities of scientific integrity and responsible conduct of research (RCR). Special focus on trauma-informed engagement, recruitment, and consent practices.

Investigator Certification Program

This Certification Series will equip prospective Clinical Investigators with the necessary skills and knowledge for conducting multi-center global clinical trials, based on a sound understanding of Good Clinical Practice (GCP), the legal framework, ethical considerations, and the roles and responsibilities of all parties involved in a trial.

The course will cover 8 sessions that will address the following:

- ☐ Drug Development
- ☐ Regulatory Affairs and CGP for Investigators
- ☐ Technology and Innovation in Clinical Trials
- ☐ Recruitment, Retention, and Diversity
- ☐ Risk Based Quality Management and Investigator Oversight
- ☐ Decentralized Clinical Trials and Discussions on Diversity
- ☐ Protocol Exploration

Upon successful completion of this series, scholars will receive the following certifications:

- ☐ ICH-GCP Certification
- ☐ Clinical Investigator Certification

Community Engagement

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1. Social and Political Determinants of Health and Their Impact on Clinical Trials Examination of risk pathways contributing to various diseases and hypothesized to be implicated in health inequities and disparities. Topics include economic and educational disadvantage, environment, and the impact of social determinants on the design, funding, and conduct of clinical trials.
2. History of Clinical Trials in Underserved Populations Examination of the history of underrepresented groups' interactions with and treatment by clinical researchers in the US. Scholars will better understand the context of underrepresented patients' mistrust of US healthcare generally, and clinical research, specifically, to explore better ways to secure patient engagement with clinical trials.
3. Community Health Centers and Clinical Trials Exploration of the role community health centers can play in increasing the participation of underrepresented groups in clinical research.
4. What Is Community-Based Participatory Research? Introduction to a public health methodology that encourages community in-reach throughout the research process. Scholars explore processes in which researchers and community members collaborate to address health disparities.
5. Community Forum on Clinical Trials Conversation with patients and other community members about their experiences with and perspectives on clinical research. Scholars and community members dialogue about the roles community members can play as advisors, collaborators, or leaders in shaping and implementing clinical trials.
6. Industry and Inclusive Research In November 2020, PhRMA member companies adopted industry-wide principles on clinical trial diversity. Scholars will learn about the movement for equity and inclusion in clinical research across industry.
7. TBD
8. TBD

Interaction Series

These sessions will focus on how to effectively engage and interact across the multidisciplinary departments and teams when conducting clinical research, including key members and departments such as clinical trials offices, biostatisticians, community outreach and engagement teams, and institutional review boards (IRB).

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Protocol Writing

The skill of writing a research protocol is a critical component of becoming a successful and independent clinical trialist. These sessions will address the fundamental principles of protocol development and the steps for writing an effective clinical research protocol.

Journal Club

The purpose of the journal club sessions is to bring the scholars together to review the latest scientific or medical literature and discuss a recent scientific paper and how it is or has the potential to change the clinical trial landscape.

Scholars will be split into groups to review and discuss. One member from each group will report out to the cohort, prompting further discussion as a whole. Discussion can center around aspects of the experimental design, critique the methods, and bring a healthy amount of skepticism (or praise) to the results, and how it is or can advance a diverse patient participation in clinical trials.

Mentorship and the Clinician-Investigator Career Path

As part of the Winn CDA tiered mentoring model, in summer 2024 Scholars will serve as pathway mentors to medical students admitted into the six-week Robert A. Winn Diversity in Clinical Trials: Clinical Investigator Pathway Program (Winn CIPP). The goal of Winn CIPP is to build the pathway of diverse future community-oriented clinical researchers by providing exposure to career pathways in clinical research at an early stage of their academic medical program.

Two sessions of the COCT will focus on the qualities of effective mentoring, and the role and significance of mentorship in career development, pathway building, and the formation of communities of practice.

Peer Group Project Discussion (Based on Winn-AACR DICT Workshop CTD Groups)

These sessions are an opportunity for scholars to meet in small groups, share their progress towards their capstone projects – developing their project concepts and protocols. Scholars will share with each other successes and challenges that they are currently experiencing with regard to increasing diversity of patient participation in their studies, and get peer feedback.

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Year 2: Developing Protocols for Community-Oriented Clinical Trials

In Year 2, the COCT curriculum equips Scholars with skills to develop protocols for community-oriented clinical trials. This more advanced sequence has six foci:

(1) Clinical Trial Design (8 sessions)
(2) Community Engagement Skills (7 sessions)
(3) Grant Writing Bootcamp (4 sessions)
(4) Mock Manuscript/Paper Review (2 Sessions)
(5) Grant Seeking / Funding Research (1 Session)
(6) Peer Group Project Discussion (4 Sessions)

Clinical Trial Design
1. Molecular Therapeutics Strategies used in the discovery and design of new biological and drug-based therapeutics resulting from analyses of signal transduction pathways critical for cancer cell proliferation and survival. Topics include approaches for identifying and validating molecular targets within pathways.
2. Prevention Trials Introduction to the science of prevention and health promotion as it pertains to clinical research. Topics include preventable causes of disease in the U.S., the etiology of disease, the role of prevention theories in the development of preventive interventions, and the role of methodology in prevention science.
3. Survival Analysis in Clinical Trials Statistical methods for analyzing and interpreting survival data arising from clinical trials. Topics include survival curves, proportional-hazard models, time dependent variables, and prognostic indices.
4. Population Health and Clinical Trials Examination of ways population health management approaches might increasingly influence the focus of clinical research and information resources available to it. Scholars will learn how population health management strategies take account of determinants of health, health outcomes, and policy interventions to improve the health of individuals and communities.
5. Ethical Issues in Epidemiology Analysis of ethical issues in epidemiological investigations. Topics include data acquisition and management, confidentiality, valid consent, advocacy, public policy, subgroup stigma, research sponsorship, conflicts of interest, communication of risk, and international and intercultural differences.
6. Biostatistics Refresher Review of biostatistics principles and methods introduced in Year 1.

7. Health Informatics The role of information systems and technology within a healthcare organization. Topics include business and technical issues in health informatics, healthcare information system design, information management, and data gathering.
8. Bioinformatics Theory and Practice Introduction to bioinformatics theory, data mining, and analysis. Topics include database searches, alignments, motif discovery, applications to gene expression analysis, next generation sequencing data and its analysis, and analysis of variation.

Community Engagement Skills

1. What Is Effective Community Outreach and Engagement? Principles and practices for leading highly effective, trauma-informed community outreach and engagement initiatives. Scholars will acquire skills to communicate effectively with different audiences; engage different stakeholder sectors dynamically; and forge productive, sustainable collaborations in the community.
2. Community Outreach and Engagement: Lessons from the Field A conversation with practicing investigators about their experiences, challenges, and successes in partnering with the community to achieve clinical trial diversity.
3. Biology vs. Community Examination of the "nature vs nurture" debate in genetics and genomics, and as it applies to the diagnosis and treatment of illnesses in underrepresented populations.
4. How Big Pharma Is Changing Population Health and Clinical Trials to Serve Communities Further discussion of initiatives by big pharma companies to increase healthcare equity in the US, with a particular focus on their impact on population health.
5. Clinical Trials in the Real World (2 sessions) Examination of pragmatic trials and research on real world data (e.g., Flatiron dataset) and exploration of real-world approaches designed to bring clinical research to underserved communities. This includes strategies to accelerate access to clinical research in underserved communities by focusing on support to investigators and the expansion/diversification of trial sites (e.g., TOPOGRAPHY, NCORP, NCATS).
6. The Use of Machine Learning and Artificial Intelligence in Underserved Communities In the past decade, advances in clinical uses of machine learning and artificial intelligence (AI) in clinical settings have yielded demonstrated benefits to patients. Scholars will learn about contemporary efforts to apply machine learning and AI in public and population health to achieve health equity.
7. Patient Advocacy Forum

Conversation about various kinds of advocacy efforts aimed ultimately at increasing the participation of underrepresented groups in clinical trials. Speakers may include patient advocates and health policy advocates addressing the significance of their roles and advocacy efforts as they pertain to clinical trials, and FDA representatives discussing how to capture the patient experience required by the FDA.

Grant Writing Bootcamp

The five sessions of this intensive grant writing workshop provide practical guidance for writing NIH R- or K-style grants. The workshop covers all critical aspects of grant writing, including how to write clear, concise Specific Aims and Research Strategy sections and Significance and Innovation statements, the NIH review process, and more.

Mock Manuscript/Paper Review

Scholars will have an opportunity to meet with experienced writers to receive formal feedback on their manuscripts or papers that they intend to submit for publication.

Grant Seeking / Funding Research

This session will provide support and resources to scholars in helping them access information and tools necessary to identify and initiate funding opportunities for clinical research, at the local, federal, and industry initiated.

Peer Group Project Discussion (Based on Winn-AACR DICT Workshop CTD Groups)

Continued small group discussions and opportunities to workshop their capstone project concepts with fellow scholars, as they refine for final capstone presentation at Annual Convening.

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM

Established by the Bristol Myers Squibb Foundation

All sessions will be held on Thursdays at 12-3pm ET/ 11am-2pm CT/ 9am-12pm PT.

Session #	Date	Session #	Date
1	Thursday, November 30, 2023	22	Thursday, May 16, 2024
2	Thursday, December 7, 2023	23	Thursday, May 23, 2024
3	Thursday, December 14, 2023	24	Thursday, May 30, 2024
4	Thursday, January 4, 2024	25	Thursday, June 6, 2024
5	Thursday, January 11, 2024	26	Thursday, June 13, 2024
6	Thursday, January 18, 2024	27	Thursday, June 20, 2024
7	Thursday, January 25, 2024	28	Thursday, June 27, 2024
8	Thursday, February 1, 2024	DICT mentoring	Thursday, August 1, 2024
9	Thursday, February 8, 2024	29	Thursday, August 8, 2024
10	Thursday, February 15, 2024	30	Thursday, August 15, 2024
11	Thursday, February 22, 2024	31	Thursday, August 22, 2024
12	Thursday, February 29, 2024	32	Thursday, August 29, 2024
13	Thursday, March 7, 2024	33	Thursday, September 5, 2024
14	Thursday, March 14, 2024	34	Thursday, September 12, 2024
15	Thursday, March 21, 2024	35	Thursday, September 19, 2024
DICT Mentoring	Thursday, March 28, 2024	36	Thursday, September 26, 2024

16	Thursday, April 4, 2024	37	Thursday, October 3, 2024
17	Thursday, April 11, 2024	38	Thursday, October 10, 2024
18	Thursday, April 18, 2024	39	Thursday, October 17, 2024
19	Thursday, April 25, 2024	40	Thursday, October 24, 2024
20	Thursday, May 2, 2024	41	Thursday, October 31, 2024
21	Thursday, May 9, 2024	42	Thursday, November 7, 2024

*NOTE: Dates are subject to change.

SCHOLARS FORUM SCHEDULE – YEAR 2 (2024-2025)*

All sessions will be held on Thursdays at 12-3pm ET/ 11am-2pm CT/ 9am-12pm PT.

Session #	Date	Session #	Date
1	Thursday, December 5, 2024	13	Thursday, June 12, 2025
2	Thursday, December 19, 2024	14	Thursday, June 26, 2025
3	Thursday, January 9, 2025	15	Thursday, July 10, 2025
4	Thursday, January 25, 2025	16	Thursday, July 24, 2025
5	Thursday, February 6, 2025	17	Thursday, August 7, 2025
6	Thursday, February 20, 2025	DICT Mentoring	Thursday, August 21, 2025

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DIVERSITY
IN CLINICAL TRIALS
AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

DICT Mentoring	Thursday, March 6, 2025	18	Thursday, September 9, 2025
7	Thursday, March 20, 2025	19	Thursday, September 18, 2025
8	Thursday, April 3, 2025	20	Thursday, October 2, 2025
9	Thursday, April 17, 2025	21	Thursday, October 16, 2025
10	Thursday, May 1, 2025	22	Thursday, October 30, 2025
11	Thursday, May 15, 2025	23	Thursday, November 13, 2025
12	Thursday, May 29, 2025		

*NOTE: Dates are subject to change.

APPENDIX E:
WINN COCT SELF-ASSESSMENT

Winn CDA (Cohort 3) Self-Assessment: Community-Oriented Clinical Trialist Competencies

Self-Assessment: Community-Oriented Clinical Trialist Competencies

Page description:
In 2014 the Joint Task Force for Clinical Trial Competency published its Harmonized Core Competency Framework for the Clinical Research Professional, with 8 core competency domains, to create a universally applicable, globally relevant competency framework for the clinical research enterprise (see https://mrctcenter.org/clinical-trial-competency/).

This self-assessment invites you to reflect on your current proficiency levels in these 8 clinical research competency domains and in a ninth domain: community-oriented research. The assessment should take 20-30 minutes to complete. Please complete your assessment by **December 15th, 2023**, to allow it to inform your Individual Professional Development Plan (IPDP) which is due January 14th, 2024.

Please note that you will revisit this self-assessment at the end of the 2-year program.

Questions? Email winncda@vcu.edu

1. First Name *

2. Last Name *

3. Email *

4. Specialty/Sub-specialties *

5. Institution *

6. Mentor Name *

Domain 1 - Scientific Concepts and Research Design

Page description:
Knowledge of scientific concepts related to the design and analysis of clinical trials.

7. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Demonstrate knowledge of pathophysiology, pharmacology, and toxicology as related to medicines discovery and development	○	○	○	○
Identify clinically important questions that are potentially testable clinical research hypotheses, through review of the professional literature	○	○	○	○
Explain the elements (statistical, epidemiological, and operational) of clinical and translational study design	○	○	○	○
Design a clinical trial	○	○	○	○
Critically analyze study results with an understanding of therapeutic and comparative effectiveness	○	○	○	○

Domain 2 - Ethical and Participant Safety Considerations

Page description:
The care of patients, aspects of human subject protection, and safety in the conduct of clinical trials.

8. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others

Compare and contrast clinical care and clinical management of research participants				
Define the concepts of “clinical equipoise” and “therapeutic misconception” as related to the conduct of a clinical trial				
Compare the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study				
Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents ensuring the protection of human participants in clinical research				
Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards				
Evaluate and apply an understanding of the past and current ethical issues, cultural variations, and commercial aspects to the medicines development process				
Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection				
Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial subjects				

Domain 3 - Medicines Development and Regulation

Page description:
Knowledge of how drugs, devices, and biologicals are developed and regulated.

9. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Discuss the historical events that precipitated the development of governmental regulatory processes for drugs, devices, and biologics	○	○	○	○
Describe the roles and responsibilities of the various institutions participating in the medicines development process	○	○	○	○
Explain the medicines development process and the activities that integrate commercial realities into the life cycle management of medical products	○	○	○	○
Summarize the legislative and regulatory framework that supports the development and registration of medicines, devices, and biologics and ensures their safety, efficacy, and quality	○	○	○	○
Describe the specific processes and phases that must be followed in order for the regulatory authority to approve the marketing authorization for a medical product	○	○	○	○
Describe the safety reporting requirements of regulatory agencies both pre- and post-approval	○	○	○	○
Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products	○	○	○	○

Domain 4 - Clinical Trial Operations (GCPs)

Page description:
Study management and GCP compliance; safety management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance); and handling of investigational product.

10. Rate your current ability to perform each of the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan	○	○	○	○
Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines	○	○	○	○
Evaluate the design conduct and documentation of clinical trials as required for compliance with GCP guidelines	○	○	○	○
Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials	○	○	○	○
Describe appropriate control, storage, and dispensing of investigational products	○	○	○	○
Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to institutional review boards/independent ethics committees (IRBs/IECs), sponsors, and regulatory	○	○	○	○

sponsors, and regulatory authorities				
Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials				
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct				
Describe the role and process for monitoring of the study				
Describe the roles and purpose of clinical trial audits				
Describe the safety reporting requirements of regulatory agencies both pre- and post-approval				
Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research				

Domain 5 - Study and Site Management

Page description:
Capabilities required at the site level to run a study (financial and personnel aspects), including site and study operations (but not encompassing regulatory/GCPs).

11. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Describe the methods utilized to determine whether or not to sponsor, supervise, or participate in a clinical trial	○	○	○	○
Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	○	○	○	○
Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	○	○	○	○
Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures, and track progress	○	○	○	○
Identify the legal responsibilities, issues, liabilities, and accountabilities that are involved in the conduct of a clinical trial	○	○	○	○
Identify and explain the specific procedural, documentation, and oversight requirements of PIs, sponsors, contract research organizations (CROs), and regulatory authorities related to the conduct of a clinical trial	○	○	○	○

Domain 6 - Data Management and Informatics

Page description:
Data acquisition and management during clinical trials, including source data; data entry, queries, quality control, and correction; and the concept of a locked database.

12. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Describe the role that biostatistics and informatics serve in biomedical and public health research	○	○	○	○
Describe the typical flow of data throughout a clinical trial	○	○	○	○
Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management	○	○	○	○
Describe the ICH GCP requirements for data correction and queries	○	○	○	○
Describe the significance of data quality assurance systems and how standard operating procedures are used to guide these processes	○	○	○	○

Domain 7 - Leadership and Professionalism

Page description:
Principles and practices of leadership and professionalism in clinical research.

13. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Describe the principles and practices of leadership, management, and mentorship, and apply them within the working environment	○	○	○	○
Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research	○	○	○	○
Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research	○	○	○	○
Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct	○	○	○	○

Domain 8 - Communication and Teamwork

Page description:
All elements of communication within a site and between the site and sponsor, CRO, and regulators, and understanding of teamwork skills necessary for conducting clinical trials.

14. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Discuss the relationship and appropriate communication between sponsor, CRO, and clinical research site	○	○	○	○
Describe the component parts of a traditional scientific publication	○	○	○	○
Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups, and the nonscientist community	○	○	○	○
Describe methods necessary to work effectively with multidisciplinary teams	○	○	○	○

Domain 9 - Community-Oriented Research

Page description:
Capabilities required to conduct research in partnership with patients and communities, and to answer research questions that matter to patients and communities.

15. Please rate your ability to perform the following functions:*

	1. Need learning and practice	2. Possess knowledge but need practice	3. Competent	4. Expert: Can teach others
Explain the relevance and benefits of patient involvement in clinical research design and implementation	○	○	○	○
Identify and set research priorities that are important to patients	○	○	○	○
Describe budgetary implications for involving and compensating patients	○	○	○	○
Describe principles of conducting work (such as obtaining informed consent) from within the cultural perspectives of patients	○	○	○	○
Describe research approaches congruent with patient and community engagement	○	○	○	○
Identify and implement strategies for successful participant recruitment and informed consent processes	○	○	○	○
Identify and implement effective participatory approaches and methods	○	○	○	○
Balance patients' perspectives with those of others on the research team	○	○	○	○
Present research results in ways that are readily understood and meaningful to lay audiences	○	○	○	○