

2025 Robert A. Winn Excellence in Clinical Trials:

Career Development Award

Application Handbook

Application Deadline: May 12, 2025 (11:59 PM ET)

Please visit <u>https://diversityinclinicaltrials.org/</u> for more information





Table of Contents

Purpose	3
Commitment	3
Award	3
Mentoring	3
Training	4
Information about Winn CIPP	4
Clinical Research Focus Area	4
Site Diversity	5
Annual Convening	5
Eligibility Criteria	5
Review of Applications	6
Key Dates	6
Application Changes	6
Award Notification	6
Application Information Use & Sharing	7
Application Procedures	7
Application Submission Checklist	8
Appendix A. Helpful Tips for Using the Application Portal	9-10
Appendix B. Full Application	11-28



<u>Purpose</u>

The Robert A. Winn Excellence in Clinical Trials: Career Development Award (Winn CDA) is part of a broader initiative, the Robert A. Winn Excellence in Clinical Trials Award Program (Winn Awards), which seeks to increase diversity in clinical trials and transform the clinical research landscape.

The Winn CDA is a 2-year program designed to support the career development of early-stage investigator physicians underrepresented in medicine, and physicians who have a demonstrated commitment to increasing diversity in clinical research, to become independent clinical trial investigators who are engaged in advancing health equity through their research and mentoring.

Commitment

- To train and develop 316 new clinical investigators dedicated to increasing diversity in clinical trials (~63/year)
- Provide opportunities to support ongoing career and leadership development in clinical research

Award

\$240k over 2 years (\$120K/year for 2 years); requires at least 40% of the scholar's time (Note: Awards will be given to organizations, not to individuals.)

It is expected that the award will cover a percentage of the scholar's salary to garner 40% of their time. Additionally, funds can be used toward a portion of a research assistant/coordinator/patient navigator salary; activities such travel and registration for presentations, publications, and other training for career development; and a limited amount for biostatistical support, and patient recruitment and/or retention activities. Funds should not otherwise be used or any study activities. If funds are used for indirect costs, the amount cannot exceed \$10,000 per year.

Mentoring

Each scholar must be mentored by an experienced clinical investigator at an established clinical trial site. If the applicant is applying with their mentor's active trial, they must participate substantively in the mentor's active clinical trial (it is not expected that scholars will have their own clinical trials). <u>*Click here for additional Mentor requirements.</u>



Training

The goal of the Winn CDA is to develop a new generation of clinical trialists. The Community-Oriented Clinical Trialist (COCT) curriculum is designed to develop and train a new generation of first-rate clinical trialists with the additional knowledge, skills, and competencies to effectively engage with communities to foster active community participation in clinical research.

The COCT training will launch with a 4 ½-day intensive educational workshop on clinical trial research methods. Winn CDA has partnered with the American Association of Cancer Research (AACR) to develop and deliver the Winn-AACR Design and Implementation of Clinical Trials (DICT) Workshop. This is a 4 ½-day training, which will introduce Scholars to foundational knowledge in state-of-the-art clinical trial design, development, implementation, and community engagement. Over the course of the 2-yr program, Scholars will participate in a fully elaborated COCT curriculum, featuring weekly or biweekly lectures by distinguished faculty, which will build and expand upon concepts presented during the Winn-AACR DICT Workshop, providing a comprehensive approach to presenting community outreach and engagement methods, skills, and strategies.

Please note:

- ★ This Workshop is a required element of the Winn CDA Program.
- ★ 2025 Winn-AACR DICT Workshop (tentatively November 2025 Dates TBA).

Please click <u>here</u> for more information about the 2024 *Winn-AACR Design and Implementation* of Clinical Trials Workshop, an essential program element to the Winn CDA.

Robert A. Winn Clinical Investigator Pathway Program (Winn CIPP) Mentoring

Each scholar will serve as a mentor to an URiM medical student during the first summer of their program. 316 URiM medical students (63/year) will participate in a 6- to 8-week summer immersion program working in community-based clinical research organizations to learn the basics of clinical trials and community outreach, education, and engagement efforts.

Clinical Research Focus Areas

Cancer, Cardiovascular Disease, and Immunologic Disorders



Site Diversity

Scholars may be practicing at urban centers/known clinical trial sites, and rural and/or trial naïve sites.

Annual Convening

An annual in-person event in the Fall 2026 and 2027 will bring key stakeholder groups together to inspire, educate, amplify and celebrate. Scholars will present their investigator-initiated clinical trial protocols in their second program year.

Eligibility Criteria

- Professional Degree
 - Eligible candidates will hold the degree of MD, MD/PhD, DO, or DO/PhD and be licensed to practice medicine on human subjects in the United States.
- Career Phase
 - Early Stage Investigator (ESI:) As defined by NIH, a new investigator who has completed their terminal research degree or medical residency/fellowship— whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant. (Applicants with an RO1 or RO1 equivalent are ineligible.)
 - *Applicants who are current fellows must be in their graduating year (expected to graduate by Summer 2025) and have a commitment from their institution towards their junior faculty position.
 - Applicants who hold concurrent career development awards (e.g., K23, K08, or any other type of career development award) are expected to have listed the funding in the application.
- Citizenship or Immigration Status
 - Eligible candidates will be US Citizens or Lawful Permanent Residents (LPRs) as defined by the US Department of Homeland Security. Applicants who hold H-1B or O-1 Visas are eligible. The visa must be valid during the full 2-year program period.

The Winn CDA Selection Committee reserves the right to evaluate and determine applicants' eligibility based on the information and justifications included in the application materials. Applicants who are uncertain about their eligibility are encouraged to contact winncda@vcu.edu for clarification and provide their CV for evaluation.



Review of Applications

The applications are reviewed by the Winn CDA Selection Committee using a multi-stage review process. Each application is assigned to at least two committee members who are leaders in their areas of expertise for independent and confidential review.

Key Dates

Online Applications Open:	January 6, 2025
Application DeadlineDue:	May 12, 2025 (11:59 PM ET)
Selection Process:	May 13-Aug 1, 2025
Award Notifications:	August 2, 2025
Award Term:	October 16, 2025 – January 15, 2028
2024 Winn-AACR DICT Workshop:	TENTATIVELY Nov 2025 - Dates to be confirmed.

Application Changes

The applicant must notify Winn CDA immediately via email (to <u>winncda@vcu.edu</u>) if any of the following conditions apply, from application submission through award notification:

- Withdrawal of Application: Inform the Winn CDA Grants and Awards team of the reason(s) for withdrawing the application. The email should include the applicant's name, the title of the proposal, and the reason for withdrawing the application.
- Change of Institution or Position: The applicant has a career plan change, leaves their current position in the institution, or is unable to meet the eligibility requirements for the program.
- Change in Eligibility Status: If the applicant is selected as a Scholar, Winn CDA has the right in its sole discretion to withdraw the award.
- Mentor Change of Institution: The applicant's mentor leaves their current position or institution.
- Change in Proposal (Scope, Timeline, Budget, etc.): The applicant has significant changes in the submitted proposal affecting aims, research strategy, timeline, and/or budget. If Winn CDA is notified of the change in proposal after the applicant is notified of an award, Winn CDA has the right in its sole discretion to withdraw the award.



Award Notification

Applicants can expect to be notified in August 2025 via email. All communication regarding applications, including award notifications, will be sent to the preferred email address on file. If you have questions, please email <u>winncda@vcu.edu</u>.

Application Information Use and Sharing

Winn CDA may use and process the information submitted through this application form for several purposes, including but not limited to: 1) evaluating the application, 2) communicating with you regarding your application and other opportunities that may be of interest to you, 3) publishing information regarding Winn CDA's grants and awards program, including through third party databases, and 4) for other legitimate purposes in keeping with Winn CDA's Privacy Policy and charitable mission. Information submitted through this application form will be kept on secure servers accessible only to third parties authorized by Winn CDA to perform functions on Winn CDA's behalf.

In addition, by submitting an application to Winn CDA, the applicant grants Winn CDA the right to use all application information submitted, outside of the research proposal, for any purpose. Winn CDA is permitted to share research proposals with reviewers, and potential supporters, and Winn CDA will require all to maintain the confidentiality of such proposals.

Application Procedures

All applications must be submitted in accordance with the requirements and instructions of this application. All application materials must be in English and must be submitted online through the Winn CDA application portal at <u>https://winnawards.smapply.io/prog/winncda/</u>. No paper applications sent by mail, email, or fax will be accepted.

Applicants are encouraged to start their application early due to the complexity of the online application process. **The full application must be submitted by 11:59 PM ET on May 12, 2025**. No late applications will be accepted.



Helpful Tips for Using the Application Portal are included in Appendix A.

Application Submission Checklist

Full application attached. Detailed instructions are noted in the application.

Listed below are the required application tasks to submit:

- Applicant Information (required)
- Training, Employment and Interest (required)
- Funding/Publication and Additional Questions (required)
- Project Information (required)
- Project Timeline Form (required)
- Project Research Strategy (required)
- Project Clinical Protocol (required)
- Project Cited References (required)
- Primary Mentor Contact Information (required)
- Primary Mentor Invitation Request (required)
- Institutional Letter of Support from Department Chair or Dean (required)
- Budget (required)
- Personal Statement Form (required)
- Applicant's Biosketch (required)
- Supporting Documentation (optional)
- Attestation of Institutional Notice and Approval (required) MUST COMPLETE ALL OTHER REQUIRED APPLICATION TASKS BEFORE COMPLETING THIS TASK

Appendix A. Helpful Tips for Using the Application Portal

Navigating the Application

- Click "Save and Continue Editing" at the bottom of the page as you go through the application or "Next" to continue to the next section.
- When finished with a particular task (e.g., Project Information), click "Mark as Complete" at the bottom of the page to validate task completion.
- If you need to edit a task after it has been Marked as Complete, click the ellipsis (...) on the top right corner of the task as shown below. Select "Edit" to reopen the form.
 - o **IMPORTANT!** Do NOT click "Reset" as this will delete previously entered data!



Receiving Notifications

Add <u>noreply@mail.smapply.net</u> and <u>winncda@vcu.edu</u> to your safe senders list to ensure you receive timely notifications associated with recommender task submissions, application submissions, etc. If you are not receiving notifications, check your junk/spam folders first, then contact <u>winncda@vcu.edu</u> for additional assistance.

Uploading a Document

- Documents should not be password protected.
- Documents must follow the file naming convention and requirements for page limits, margins, and fonts (see individual application sections for details). If any document you uploaded does not meet the specific criteria, Winn CDA will return your application.
- To upload a document, click "Attach File" and select the file to be uploaded.
- To edit a file name, click the ellipsis (...) next to the file name as shown below. Select "Edit" and enter the new file name based on the file naming convention.
- To remove or replace an uploaded document, click the ellipsis (...) next to the file name as shown below. Select "Remove" then click "Attach File".

Budget Filename: Added: Feb 17 2021	
	Edit
	Preview
	Remove
	Download

Inviting a Mentor

- As part of your application process, you will need to "Request a Recommendation" from third parties such as a Mentor and Institution Approver. Click on the task and fill in the details of the Mentor including the First Name, Last Name, Email, and a brief message (optional) to send the Mentor. Once the information is submitted, an automated email will be sent to the Mentor letting them know that they've been asked to provide a recommendation. When the recommendation is submitted, you will be instantly notified.
- If the Mentor didn't receive an email invite, confirm that you sent the invite to the correct email address and there are no spelling errors, ask the Mentor to check their junk/spam folder, or resend the Invitation.
- To resend or withdraw the request, click the ellipsis (...) near the Recommender's name and email and select the appropriate option from the drop-down list as shown below.
- If the Mentor still has not received the email, please contact <u>winncda@vcu.edu</u>.

	nplete a recommendation for your application. Make : ddress associated with their ASCO membership accou	
therwise this recommendation ystem.	will not be available to your mentor when they log int	to the
Recommendations	You will not be able to review the contents of received rec	ommendations.
Recommendations Mentor name & email		commendations.
	You will not be able to review the contents of received rec Requested: Dec 16 2019	ommendations.
Mentor name & email		Resend request

Application:

Robert A. Winn Career Development Award (Winn CDA)

Applicant Information

Incomplete

Form for "Applicant Information"

First Name

(No response)

Middle Name

(No response)

Last Name

(No response)

Primary Email Address (all future communications about the application will be sent to this address)

(No response)

Alternate Email Address

Phone Number (please use XXX-XXX-XXXX format)

(No response)

Mailing Address

(No response)

City

(No response)

State

(No response)

Zip Code

(No response)

I identify my gender as:

(No response)

Pronouns

*Mark all that apply

No Responses Selected

I identify my race/ethnicity as (please select all that apply):

No Responses Selected

Citizenship/Immigration Status

(No response)

Age Range

(No response)

NPI Number

(No response)

Training, Employment, Interest

Incomplete

Form for "Training, Employment, Interest"

What is your medical degree?

Please list all active licenses and board certifications, including but not limited to:

- State Medical Boards
- United States Medical Licensing Examination (USMLE)
- American Board of Medical Specialties
- · American Osteopathic Association's Bureau of Osteopathic Specialists

(No response)

Date you completed your terminal research degree or end of post-graduate clinical training.

If you do not have the exact date, please list year:

As a reminder, applicants must be considered an Early Stage Investigator (ESI).

As defined by NIH, a new investigator who has completed their terminal research degree or clinical training whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant. (Applicants with an RO1 or RO1 equivalent are ineligible.)

(No response)

Please list any post-graduate clinical training and the completion date (MM-YYYY):

(No response)

*If you are applying as a fellow, you must be in your graduating year (expected to graduate by Summer 2025) and have a commitment from your institution towards your junior faculty position.

Please confirm the date of graduation.

(No response)

Please list your specialty sub-type (i.e. Surgical vs. medical vs. radiation oncology vs. pediatric):

(No response)

What is your planned Clinical Research Focus Area for Winn CDA?

Research conducted under Winn CDA must be within one of these three therapeutic areas. Please choose the one that is most aligned with your research project.

(No response)

Please select the clinical specialty you would like to work on during this program and specify the disease your research will focus on:

(No response)

What is your current job title?

(No response)

What is the name of your current employer?

Date started:

(No response)

What is the street address of your employer?

(No response)

What is the city of your employer?

(No response)

What state is your employer in?

(No response)

Do you expect to transfer institutions at the time of awarding and contracting (August/September 2025)?

(No response)

What is your practice environment (i.e. Urban vs. suburban vs. rural)?

(No response)

Please attach your CV here: (within the last 6-months)

Use this file naming convention – [last name first name CV] (i.e. Smith John CV)

Funding and Publications

Incomplete

Form for "Funding and Publications"

Current Sources of Salary Support and/or Other Funding

Using the template provided <u>here</u>, please list all current sources of funding including: Name of funder, Amount, Funding Period, Percentage of time spent, Renewable, and Brief Summary/Description.

Upload Funding Sources Template

Use this file naming convention - [last name first name Funding Sources] (i.e. Smith John Funding Sources)

Publications

Please list all significant publications within the last 3 years.

Please include Peer Review status. Specify if an abstract or manuscript.

If none, leave blank.

(No response)

Additional Questions

Incomplete

Form for "Additional Questions"

Please tell us how you heard about this program. Please include name(s) of referring individual or organization, if applicable.

(No response)

Did you participate in a Winn CDA Informational Webinar?

(No response)

Project Information

Incomplete

During the Winn CDA you are required to participate in an active clinical trial. In most cases, the project will be that of your mentor; in some cases it may be your own project. This section solicits the information about the clinical trial you will be working on.

Form for "Project Information"

Project Research Focus Area(s): Select one

(No response)

Project Disease Focus: What specific disease or condition will your project address?

(No response)

Type of Research Study: Select one.

(No response)

Will the project serve or recruit from rural communities?

(No response)

Research Project Title (75 words maximum): Provide a short descriptive title of the research project.

(No response)

Research Project Description/Abstract (650 words maximum): Provide a brief abstract of the research project.

Lay Abstract (500 words maximum): Provide a layperson summary of the project. Describe the work in a way that it would be understood by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms when possible. It should not include confidential information. If selected to receive an award, the Winn CDA may use the contents of this summary on its website and/or other public facing materials.

(No response)

Specific Aims (300 words maximum per aim): Select the number of aims from the dropdown list. Use a separate text box for each aim. Succinctly list the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field or develop new technology). The specific aim should concisely and realistically state what the research intends to accomplish and/or what hypothesis is to be tested, and should list measurable objectives.

(No response)

Assurances

Human Subjects - Indicate whether human subjects will be involved in the research. If yes, select the appropriate status below.

(No response)

If the study is a drug trial, please enter the name of the drug(s) and the drug manufacturer(s). It is highly encouraged to include a letter from the manufacturer(s) or supplier(s) that they will provide the drug in the Supporting Documentation section of the application.

(No response)

Project Timeline

Incomplete

Please use the template provided <u>here</u>.

Enter each major project milestone/activity, a brief description, the expected completion date, the status and if it is an associated deliverable. A deliverable is something that can be included in a progress report, such as a publication or an approval letter. You are not required to have deliverables; however, the timeline should make it clear what outcomes will be achieved during the grant award period.

Download the template, then update the following:

- Enter the name of the milestone/activity
- Enter a description of the milestone/activity
- Enter the expected date of completion
- Indicate whether the milestone/activity is a deliverable
- Select the appropriate status
- Do not enter any comments.

Click "Attach File" and select the file to be uploaded in the application.

If possible, use this file naming convention - [last name first name Project Timeline] (i.e. Smith John Project Timeline).

After completing this form, click "Mark as Complete".

Project Research Strategy

Incomplete

Please describe the research strategy of the clinical trial of which you are applying.

The project referenced here should be the same project outlined in the Project Information section of this application.

If you are applying with your mentor's trial, please address the questions below with a focus on your role in that trial where applicable.

The research strategy is limited to six (6) typewritten, single-spaced pages, with one-inch margins and using an 11point Arial font type. ALL pertinent tables, pictures, and graphs MUST be included within the 6-page limit. When in preview mode, it may look like there are more than 6 pages.

The Research Strategy must contain the following information:

1. Significance and Background:

- Explain the importance of the problem or critical barrier to progress in the field that the project addresses.
- Explain how the project will improve scientific knowledge, technical capability, and/or critical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will change if the aims are achieved.

2. Innovation:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. Approach:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Describe the rationale for how the exclusionary criteria for enrolling patients was designed.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- Clearly state the applicant's role in the project (e.g., performing the assays, patient recruitment strategies, etc.). When human subjects are involved, the precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained.

• List and describe the facilities and resources available to conduct the study, including a description of industry support for any clinical trials.

4. Accrual of Diverse Patients

- Discuss your goals for accruing patients from groups underrepresented in medicine (UiRM).
- Describe your proposed strategy and methodology for enrolling and retaining URiM patients.
- Discuss potential problems, alternative strategies, and benchmarks for success in accruing URM patients.

Click "Attach File" and select the file to be uploaded in the application.

If possible, use this file naming convention – [last name first name Research Strategy] (i.e. Smith John Research Strategy).

After completing this form, click "Mark as Complete".

Project Clinical Protocol

Incomplete

Form for "Project Clinical Protocol"

Project Protocol Title

(No response)

Project Protocol Type (i.e. Phase 3 vs post-marketing, etc.)

(No response)

Upload a Protocol Summary. Please use the word template and refer to the instructions.

If possible, use this file naming convention – [last name first name Protocol Executive Summary] (i.e. Smith John Protocol Executive Summary).

Project Cited References

Incomplete

Upload a bibliography of any references cited in the Research Plan. Click "Attach File" and select the file to be uploaded in the application.

If possible, use this file naming convention: [last name first name Cited References] (i.e. Smith John Cited References).

After completing this form, click "Mark as Complete".

Primary Mentor Contact Information

Incomplete

Form for "Primary Mentor Information"

Please enter the contact information for your primary mentor.

Primary Mentor First Name

(No response)

Primary Mentor Last Name

(No response)

Primary Mentor Email Address (this will be the primary way we contact your mentor.)

(No response)

Primary Mentor Phone Number

Please use XXX-XXX-XXXX format.

(No response)

Primary Mentor Title

(No response)

Primary Mentor Institution

(No response)

Primary Mentor Invitation Request

Incomplete

All Winn CDA awardees must designate at least one primary mentor for clinical trial research and career development mentoring. If you appoint a mentoring team, you must designate a **primary mentor*. It is strongly encouraged that the primary mentor be from your sponsoring institution. In most cases, applicants will participate in the active clinical trial of the primary mentor. **Please note the mentor stipend will only go to the applicant's <u>primary mentor</u>.*

For more information please use 2024's <u>Mentor Handbook</u> as a reference. A formal handbook for 2025 will come out later this year.

To request a recommendation from your mentor:

- Click "Request a Recommendation".
- Enter the First name, Last name, Email address, and a brief message (optional) to the mentor.
- Click "Send Request".
- The primary mentor will receive an email with an invite to complete the recommendation by submitting:
 - Primary Mentor Biosketch (Template and Example)
 - Primary Mentor Letter of Support
 - Primary Mentorship Plan (Template)

**Please note: It will appear to to the mentor that there is one task, but in that one task the mentor can upload all 3 documents separately or as one pdf within the same task. The mentor must upload ALL documents before they submit. The mentor will only be able to submit ONCE. Please be sure to have uploaded ALL documents BEFORE you hit submit.

• When they click "Start" they will be asked if they wish to Accept or Decline the recommendation request from the applicant. Upon accepting, the mentor will be able to complete and submit the recommendation within the site.

***Applicants will receive a notification when the recommender accepts this invitation.

 Note: This task will appear with a 'half full circle', which means that the request was successfully sent to the mentor. It does not mean the mentor uploaded their required documents.

*** Applicants will receive a notification when your mentor completes their task. Once your mentor has completed their task, please come back to the Mentor Invitation Request task and Mark it Complete. Once that and all other prior tasks are Marked Complete, the Institution Approval Task will become available to you for completion.

To re-send or withdraw the request, click the ellipsis (...) near the mentor's name and email and select the appropriate option from the drop-down list.

IMPORTANT: The mentor must complete their task and click "Submit" prior to the application deadline. The applicant <u>will not</u> be able to submit the application until these tasks are submitted. Once the mentor has submitted their documents, return to this task and click "**Mark as Complete**".

Recommenders

Institutional Letter of Support from Department Chair or Dean

Incomplete

A letter from the Department Chair or Dean from the applicant's sponsoring institution where the research project will be conducted must be provided. This letter must include a statement of institutional support that will ensure the applicant will be afforded the <u>40% protected time</u> (e.g., percentage time allocated for CDA activities) and commitment of institutional resources needed to perform the proposed research. <u>This letter must be signed and on official letterhead</u>.

If the letter is not signed and not printed on official letterhead, the application will be rejected and returned.

Note: If the mentor is the Department Chair, the Institutional Letter of Support must come from the Dean.

Click "Attach File" and select the file to be uploaded in the application.

If possible, use this file naming convention – [last name first name Institutional LOS] (i.e. Smith John Institutional LOS).

Budget

Incomplete

Please find the Budget Template here.

The award funds are primarily to protect a minimum of 40% of your time for required program components.

Some required program components, but not limited to, are:

- clinical trial activities
- virtual orientation
- the 4.5-day intensive Winn-AACR Design & Implementation of Clinical Trials Workshop (tentatively November 2025) **not to be included in program budget; travel will be covered by the AACR
- the two-year Community-Oriented Clinical Trialist Training, including weekly (year 1) and bi-weekly (year 2) Winn CDA Scholars Forums
- career development planning
- Winn CIPP student summer mentoring
- Annual Convenings **not to be included in program budget; travel will be covered by the host
- reporting

Budget Guidelines:

•<u>Total Award</u>: The total award amount is payable on or about November 1st in annual increments of \$120,000 over two years. The total budget requested per year must not exceed \$120,000. The total budget requested must be no more than \$240,000 for the 2 years. It is expected that the award will cover a percentage of the Scholar's salary to garner 40% of their time.

•<u>Salary support</u>: It is recommended to allocate \$100,000 per year to support the protected 40% of the Scholar's effort. Institutions may allocate less or up to the full \$120,000, regardless of sources of salary support as long as the 40% of the Scholar's effort to Winn CDA remains protected. The 40% protected time does not necessarily have to correlate directly with 40% of the Scholar's salary. We are aware that salaries may differ from awardee to awardee. If salary support is coming from other funding sources, please note that in the justification column and explain how the 40% protected efforts on behalf of Winn CDA will remain protected.

•<u>Indirect costs:</u> Up to \$10,000 of the award, per year, may be applied to overhead or facilities and administrative cost of the applicant's institution in administering the research project.

•<u>Discretionary funds</u>: Remaining funds should be specifically allotted to essential personnel related to conducting the study such as a portion of a research assistant, coordinator, manager, or patient navigator salary.

•Allowance of up to \$10,000 that could be used to support a limited number of specific project-related costs. For example: 1) costs related to patient recruitment/retention (e.g., compensation/incentives to participate, expenses for travel related to study participation); 2) costs for biostatistics support/consultation.

•Funds can be allocated to scholar career development activities. For example: 1) conference attendance/travel; 2) publication costs; training fees

**Attendance at all program Workshops and the Winn CDA Annual Convenings is required; <u>these costs will be</u> <u>covered by the program and should not be reflected in the budget document.</u> Meeting requirements include:

- Day 1 Virtual Orientation
- Winn-AACR Design and Implementation in Clinical Trials Workshop (4.5-day intensive, in person training will typically take place in November 2025 tentative dates are November; confirmation later this spring).
- Weekly/Bi-weekly Winn CDA Scholars Forum every Thursday from 12:00-3:00PM ET Scholars are required to attend as live virtual participants via Zoom in a minimum of 80% of the forum sessions. Scholars are required to submit a post-webinar quiz after each forum.
- Two 1.5 day Annual Convenings in November at the end of program years 1 and 2 (Dates and locations TBD)

Budget Timeline:

The Award Term is for a full 27 months from October 16, 2025 – January 15, 2028. The budget can be for the 24 month period to align with your finance and operational requirements at your institution. Or your budget can be paced to match the full award term of 27 months. If you opt for the 24 month period budget timeline, then you will still

have the remaining 3 months to expend any unused funds without requesting a formal No Cost Extension and to complete any remaining program deliverables.

***During the award period, at least \$80,000 of the year 1 budget must be expended by the end of each reporting year as a condition of approval for new funds. If at least \$80,000 of the year 1 budget is not expended, you will need to include a justification as to why there was significant underspending.

If possible, use this file naming convention – [last name first name Budget] (i.e. Smith John Budget).

After completing this form, click "Mark as Complete".

Personal Statements

Incomplete

Enter answers to the following questions. You may cut and paste from a Word document. **Each response is limited to 500 words.**

<u>Your commitment to diversity</u>. Describe your commitment to promoting diversity in clinical trials throughout your career and how you see this program advancing your ability to do so.

<u>Clinical trial experience</u>. Describe your experience with clinical trial design or participation in clinical trial research.

Your career plan. Provide a brief description of your career plan.

Impact of award on your career. Provide a brief explanation of how receiving this award would affect your career.

Percentage time of research activities. Provide the percentage of time you will spend on total research activities.

Your role. Describe briefly your role versus your mentor's role in the proposed research study.

<u>Collection and support of data.</u> Briefly describe who will collect and analyze the data.

<u>Clinical potential of research project.</u> Briefly describe the clinical potential of this research project.

<u>Other funding sources.</u> List other funding agencies/organizations where this research proposal was or will be submitted. If none, please indicate N/A.

After completing this form, click "Mark as Complete".

Form for "Personal Statements"

Enter answers to the following questions. You may cut and paste from a Word document. **Each response is limited to 500 words.**

<u>Your commitment to diversity</u>. Describe your commitment to promoting diversity in clinical trials throughout your career and how you see this program advancing your ability to do so.

<u>Clinical trial experience</u>. Describe your experience with clinical trial design or participation in clinical trial research.

(No response)

Your career plan. Provide a brief description of your career plan.

(No response)

<u>Impact of award on your career</u>. Provide a brief explanation of how receiving this award would affect your career.

(No response)

<u>Percentage time of research activities</u>. Provide the percentage of time you will spend on total research activities.

(No response)

Your role. Describe briefly your role versus your mentor's role in the proposed research study.

(No response)

<u>Collection and support of data.</u> Briefly describe who will collect and analyze the data.

<u>Clinical potential of research project.</u> Briefly describe the clinical potential of this research project.

(No response)

<u>Other funding sources.</u> List other funding agencies/organizations where this research proposal was or will be submitted. If none, please indicate N/A.

(No response)

Applicant's Biosketch

Incomplete

Applicants should use the NIH Biosketch template provided.

The Biosketch must not exceed five (5) pages. To complete the Biosketch, please refer to these instructions.

<u>Click here</u> for the Biosketch template. <u>Click here</u> for the Biosketch example.

Click "Attach File" and select the file to be uploaded in the application.

If possible, use this file naming convention - [last name first name Biosketch] (i.e. Smith John Biosketch).

After completing this form, click "Mark as Complete".

Supporting Documentation (optional)

Incomplete

** If you do not have any supporting documents to upload, you do not need to complete this task.

This section may be used to upload any necessary additional information required to properly review the application (e.g., letters documenting the feasibility of the project, a letter from a drug company that they will provide the investigational drug, a letter of collaboration from another laboratory providing expertise for this project, a letter of support for a collaboration, letters of support from secondary mentors, etc.). Applicants are encouraged to provide a letter of support for any investigational agents and letters of support from collaborating biostatisticians. Due to the limited time given to the reviewers, upload of any documents that are not critical to the review of the proposal or any additional publications is not allowable.

Click "Attach File" and select the file to be uploaded in the application. Repeat this step to upload multiple files.

If possible, use this file naming convention for each document: [last name first name Supporting Document 1] (i.e. Smith John Supporting Document 1; Smith John Supporting Document 2, etc.).

After completing this form, click "Mark as Complete".

Attestation of Institutional Notice and Approval

Incomplete

You will not be able to navigate to this page until all required sections have been "Marked as complete".

Applicants are expected to notify their grants team or office of sponsored research of their application to Winn CDA within an appropriate time frame.

This task is an attestation that you have notified your grants team or office of sponsored research that you are applying to Winn CDA, and that they have given you approval to submit your application.

Form for "Institutional Notice and Approval"

Applicants are expected to notify their grants team or office of sponsored research of their application to Winn CDA within an appropriate time frame.

Please enter your name below to attest that you have notified your grants team or office of sponsored research that you are applying to Winn CDA, and that they have given you approval to submit your application.

(No response)

Information to share with your grants team or office of sponsored research.

Winn CDA Cohort 5 is funded by Bristol Myers Squibb Foundation (BMSF), Gilead Sciences, Amgen, and Genentech. VCU Massey Comprehensive Cancer Center is the lead implementation partner - via the Medical College of Virginia Foundation (MCVF).

The Winn CDA funds for scholars are disbursed by MCVF to the scholar's institution. The scholar's award will be sponsored by one of the funding partners - sponsor designation will be assigned at the time of awarding.

Below is MCVF's information if needed by your grants team/office of sponsored research:

- Medical College of Virginia Foundation
- 1228 E. Broad St. Box 980234
- Richmond , VA 23298
- EIN: 54-6053660

Click <u>here</u> for more information from MCVF to share with your grants team/office of sponsored research if needed.