# 2024 Robert A. Winn Diversity in Clinical Trials:

# Career Development Award

# Application Handbook

**Application Deadline: May 13, 2024 (11:59 PM ET)**

Please visit https://diversityinclinicaltrials.org/ for more information

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**Purpose**

The Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA) is part of a broader initiative, the Robert A. Winn Diversity 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 308 new clinical investigators dedicated to increasing diversity in clinical trials (~60/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 and participate substantively in the mentor's **active** clinical trial (it is not expected that scholars will have their own clinical trials).

**\*Click here for additional Mentor requirements.**

**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.***
★ ***2024 Winn-AACR DICT Workshop dates: November 18-22, 2024.***

Please click **here** for more information about the 2023 *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. 308 URiM medical students (60/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 2025 and 2026 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 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 2, 2024 |
| Application DeadlineDue: | May 13, 2024 (11:59 PM ET) |
| Selection Process: | May 15-Aug 1, 2024 |
| Award Notifications: | August 2, 2024 |
| Award Term: | October 15, 2024 – January 15, 2027 |
| 2024 Winn-AACR DICT Workshop: | November 18-22, 2024. |

## Application Changes

The applicant must notify Winn CDA immediately via email (to winncda@vcu.edu) 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 2024 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 winncda@vcu.edu.

## 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 https://winnawards.smapply.io/prog/winncda/. 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 13, 2024. No late applications will be accepted.

An Authorized Official representing the sponsoring institution (typically from the institution's Office of Sponsored Research) must approve the completed application before submission by completing the "Institution Approval" task. Notify your Authorized Official immediately of your intent to apply to allow them ample time to prepare for the "Institution Approval" task they must complete by May 20, 2024 at 5:00 PM ET.

Any updated supporting documentation (e.g., 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, etc.) must be sent to

winncda@vcu.edu no later than 11:59pm ET on May 20, 2024. Please note that these documents are optional, and only updates to documents submitted by the May 13th deadline 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)
- ☐ Institutional Approval (required)
- ☐ Review and Submit (required)

**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 noreply@mail.smapply.net and winncda@vcu.edu 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 winncda@vcu.edu 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".
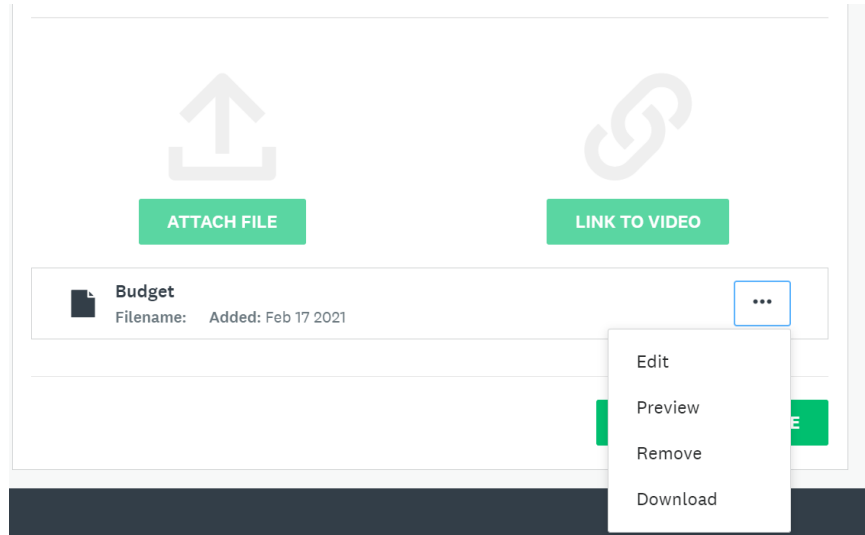
**Inviting a Mentor**

- 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 winncda@vcu.edu.
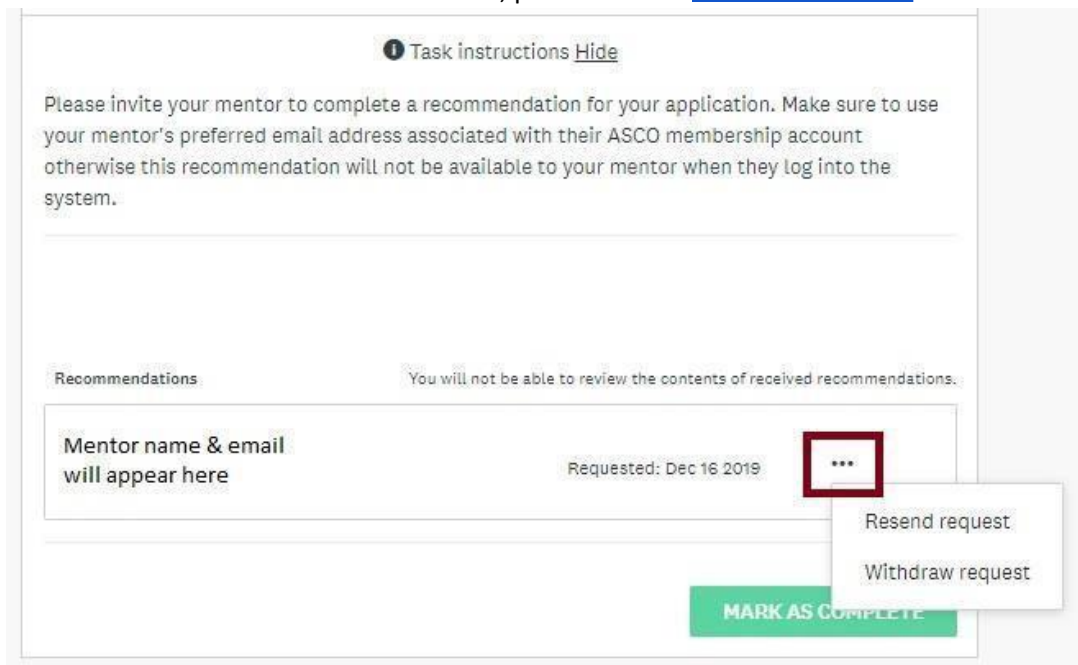
# Application:

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

(No response)

**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?**

(No response)

**Medical License and Board Certification**

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)

**Please list your specialty:**

(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?**

(No response)

**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 (August 2024)?**

(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) Please do not use special characters when saving/naming file.

# Funding and Publications

**Incomplete**

# Form for "Funding and Publications"

**Current Sources of Salary Support and/or Other Funding**

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

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**Upload Funding Sources Template**

Use this file naming convention – [last name first name Funding Sources] (i.e. Smith John Funding Sources) Please do not use special characters when saving/naming file.

---

**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)

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**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 following information about the clinical

trial you will be working on (all are required):

- Research Focus Area(s): Select one. (Cancer, Cardiovascular & Immunologic)
- Disease Focus: What specific disease or condition will your project address?
- Research Project Title (75 words maximum): Provide a short descriptive title of the research project.
- 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.
- Specific Aims (1250 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.
- Type of Research Study: Select from the drop-down list (Drug Treatment Trial or Non-Drug Treatment Clinical Trial)
- Assurances:
  - Human Subjects: Indicate whether human subjects will be involved in the research. If yes, select the appropriate status.
    - If the status is Approved, enter the IRB Approval Date, IRB Expiration Date, and Assurance Number.
    - If the status is Pending, please provide the submission date and the expected approval date if known.
    - If the status is Exempt, enter the Exemption Number.
  - Use of Drug(s): Indicate if the research involves the use of drug(s).
    - If yes, 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.

# 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)

**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.**

(No response)

**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** *(1250 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)

**Type of Research Study: Select from the drop-down list (Drug Treatment Trial or Non-Drug Treatment Clinical Trial)**

(No response)

**Assurances**

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

(No response)

**Use of Drug(s) - Indicate if the research involves the use of drug(s).**

(No response)

# Project Timeline

**Incomplete**

Please use the template provided **here**.

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.

Use this file naming convention – [last name first name Project Timeline] (i.e. Smith John Project Timeline) Please do not use special characters when saving/naming file.

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 11-point Arial font type. ALL pertinent tables, pictures, and graphs MUST be included within the 6-page limit.

**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. <u>Innovation:</u>

- 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. <u>Approach:</u>

- 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. <u>Accrual of Diverse Patients</u>

- 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.

Use this file naming convention – [last name first name Research Strategy] (i.e. Smith John Research Strategy) Please do not use special characters when saving/naming file.

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. Download the [template](#) and the [instructions](#).**

Use this file naming convention – [last name first name Protocol Executive Summary] (i.e. Smith John Protocol Executive Summary) Please do not use special characters when saving/naming file.

## 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.

Use this file naming convention: [last name first name Cited References] (i.e. Smith John Cited References) Please do not use special characters when saving/naming file.

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.

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](#))**
- 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 **will not** 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"**.

*\*Please note the mentor stipend will only go to the applicant's <u>primary mentor.</u>*
**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 protected time (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.

Use this file naming convention – [last name first name Institutional LOS] (i.e. Smith John Institutional LOS) Please do not use special characters when saving/naming file.

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

# 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 (clinical trial activities; virtual orientation; the 4.5-day intensive Winn-AACR Design & Implementation of Clinical Trials Workshop (tentatively November 18-22, 2024); 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; and reporting). Award funds may not be applied to patient care costs that are reimbursable by a third-party payer.

**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.

•<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 a small amount per year (e.g., up to $5000) 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

*During the award period, at least 80% 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% of the year 1 budget is not expended, you will need to submit a

request for a no cost extension for the remaining unused funds, and include a justification as to why there are 20% or more of the budgeted funds remaining.

*Attendance at all program Workshops and the Winn CDA Annual Convenings is required; these costs will be covered by program and should not be reflected in the budget document. 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 2024 - tentative dates are November 18-22, 2024; confirmation later this spring).
- Weekly/Bi-weekly Winn CDA Scholars Forum – every Wednesday 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)

Use this file naming convention – [last name first name Budget] (i.e. Smith John Budget) Please do not use special characters when saving/naming file.

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.**

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

Clinical trial experience. 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.

Collection and support of data. Briefly describe who will collect and analyze the data.

Clinical potential of research project. Briefly describe the clinical potential of this research project.

Other funding sources. 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.**

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

(No response)

**Clinical trial experience.** 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)

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

(No response)

**Percentage time of research activities**. 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)

**Collection and support of data.** **Briefly describe who will collect and analyze the data.**

(No response)

**Clinical potential of research project.** **Briefly describe the clinical potential of this research project.**

(No response)

**Other funding sources.** **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 with an expiration date of 09/30/2024. The Biosketch must not exceed five (5) pages. To complete the Biosketch, please refer to these instructions.

**Click here** for the Biosketch template. **Click here** for the Biosketch example.

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

Use this file naming convention – [last name first name Biosketch] (i.e. Smith John Biosketch) Please do not use special characters when saving/naming file.

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

# Supporting Documentation (optional)

**Incomplete**

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, 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.

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.) Please do not use special characters when saving/naming file.

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

# Institutional Approval

**Incomplete**

The head of your institution's Office of Sponsored Research, the authorized official representing the sponsoring institution, must approve the completed application by completing the "Institutional Approval" task.

***Please note: This task will not be available until all the prior required application tasks have been completed, including the mentor recommendation. Applicants will receive a notification when your mentor completes their task. Once your mentor has completed their task, please go 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 request a recommendation from the Institution Approver:
- Click "Request a Recommendation".
- Enter the First name, Last name, Email address, and write a message (optional) to the Institution Approver.
- Click "Send Request". The Institution Approver will receive an email notification with the message.
- If the Institution Approver accepts or declines the recommendation request, the applicant will receive an email notification.

    **\*\*\*Note: This task will appear with a 'half full circle', which means that the request was successfully sent to the institution. It <u>does not mean</u> the institution uploaded their required documents.\*\*\***

- To resend or withdraw the request, click the ellipsis(…) near the Institution Approver's name and email and select the appropriate option from the drop-down list.
- IMPORTANT: The Institution Approver must complete their task and click "Submit" at the bottom of the page prior to their deadline. An email notification will be sent to the applicant confirming that the task has been completed.
- <u>The applicant will be able to submit the application once the request has been sent, but the application is not considered complete until the Institution Approval is submitted.</u>
- Once the Institution Approver request has been sent, click **"Mark as Complete"**.

**Recommenders**

# Review your application

**Incomplete**

You will not be able to navigate to this page until all required sections have been **"Marked as complete"** and all tasks from the Mentor and Institution Approver have been submitted.

After you mark this task as complete, on the left navigation, click **"Review"** to review or **"Submit"** to submit the application (these options are located on the left-side of the screen).

To download a copy of the application, click **"My Applications."** Click the ellipsis(...) on the specific application and click **"Download".**

On the next screen, select the desired options and click **"Download".**

A new tab will open. Once the download is ready, click **"Download"**. The application will be downloaded as a zip file.