2023 Robert A. Winn Diversity in Clinical Trials: Career Development Award

Application Handbook

Application Deadline: May 12, 2023 (11:59 PM ET)

Please visit www.diversityinclinicaltrials.org
for more information

About the Bristol Myers Squibb Foundation

The Bristol Myers Squibb Foundation empowers partners to build innovative solutions to advance health equity and improve access to quality healthcare for patients by focusing grant making on communities most at risk of suffering the impacts of serious diseases in the regions of the world that are hardest hit.

For more information, visit BMS.COM/FOUNDATION

About Virginia Commonwealth University

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 https://vcu.edu/ and https://www.vcuhealth.org/ .

About 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.

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.

Table of Contents

Purpose
The Bristol Myers Squibb Foundation (BMSF) in partnership with Virginia Commonwealth University (VCU) has developed the Robert A. Winn iversity in Clinical Trials: Career Development Award (Winn CDA) to tackle low clinical trial recruitment of diverse patients by intentionally training clinical investigators committed to increasing diversity in clinical trials. This program provides early stage clinical investigators with distinct training, skills, and support to initiate and conduct clinical trials that support the recruitment of underrepresented patients.

Funding Available
Awards are $120K/year for 2 years to garner at least 40% of the participant's time for program participation during the award period. View Winn CDA program requirements.

Awards will be made to organizations, not to individuals.

Guidance for the award: It is expected that the award will cover a percentage of the Scholar's salary to garner 40% of their time. The budget guideline is to allocate $100,000 per year to salary support to protect the Scholar's time, although institutions may allocate the full $120,000 to the Scholar's salary. Funds not allocated to the Scholar's salary may be used toward a portion of a research assistant/navigator salary. If funds are used for indirect costs, the amount cannot exceed $10,000 or 10% of the recommended salary offset.

Eligibility Criteria

Candidate Profile

In determining eligible candidates for the Winn CDA program, the following racial/ethnic groups are designated as "underrepresented in medicine":
- African American or Black
- Hispanic or Latine
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Southeast Asian (please specify)
- Non-URM

OR have a demonstrated commitment to increasing diverse patient participation in clinical trials

Professional Degree
Eligible candidates will hold the degree of MD, MD/PhD, DO or DO/PhD

Career Phase

Early Stage Investigator (ESI) As defined by NIH, a new investigator who has completed his or her terminal research degree or medical residency—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 3, 2023
Application DeadlineDue:	May 12, 2023 (11:59 PM ET)
Selection Process:	May 15-Aug 1, 2023
Award Notifications:	August 3, 2023
Award Term:	October 1, 2023 – October 31, 2025

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:

1. 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.

2. Change of Institution or Position: The applicant has a career plan change, leaves his/her current position in the institution, or is unable to meet the eligibility requirements for the program.

3. 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.

4. Mentor Change of Institution: The applicant's mentor leaves his/her current position or institution.

5. 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 2023 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, third party contractors, 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. For example, 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 before the application deadline. The full application must be submitted by **11:59 PM ET on May 12, 2023**. No late applications will be accepted.

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 19, 2023**. 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 Guide

Sections of the full application are listed below. More details about each section, including requirements and instructions, are described in the next pages.

- Applicant Information (required)
- Training, Employment and Interest (required)
- Funding/Publication and Additional Questions (required)
- Project Information (required)
- Mentor Invite (required)
- Mentor Biosketch (required)
- Letter of Support (required)
- Project Timeline Form (required)
- Personal Statement Form (required)
- Budget (required)
- Applicant's Biosketch (required)
- Research Strategy (required)
- Cited References (required)
- Institutional Letter of Support from Department Chair or Dean (required)
- Clinical Protocol - Executive Summary (required)
- Supporting Documentation (optional)
- Institutional Approval (required)
- Review and Submit (required)

Applicant Information

- First Name
- Middle Name
- Last Name
- Primary email address (all future communications about the application will be sent to this address)
- Alternate Email Address
- Primary phone number
- Mailing Address
- Gender
- Ethnicity
- Citizenship/Immigration Status
- Age Range
- NPI Number

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

Training, Employment and Interest

- What is your degree?: Select one. (MD, MD/PhD, DO, DO/PhD)
- Date you completed your terminal research degree or end of post-graduate clinical training. If you do not have the exact date, please list the year.
- Please list any post-graduate clinical training and the completion date (MM-YYY)
- Please list your specialty
- Please list your specialty subtype: (i.e., Surgical vs. medical vs. radiation oncology vs. pediatric)
- Please list the clinical specialty you would like to work on during this program:
    - Oncology - Solid Tumor (List Cancer Type)
    - Oncology - Hematology (List Cancer Type)
    - Cardiovascular Disease (List Specific Disease)
    - Immune-Mediated Disease (List Specific Disease)
- What is your current job title?
- What is the name of your employer?
- Date started:
- What is the street address of your employer?
- What is the city of your employer?
- What state is your employer in
- What is your practice environment (i.e., Urban vs. suburban vs. rural)?

Funding/Publication and Additional Questions

Current sources of Salary Support and Other Funding. Using this template provided here, please list all current sources of funding including:

- Name of funder
- Amount
- Funding period
- Percentage of time spent
- Renewable
- Brief summary/description

Publications:

- Please list all significant publications within the last 2-3 years. Please include peer review status. If none, leave blank.

Additional Questions:

- Please tell us how you heard about this program. Include name(s) of referring individual or organization if applicable
- Did you participate in a Winn CDA Informational Webinar: select one (yes, no)

Project Information

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 Disease & 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:** 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.

After completing this form, click **“Mark as Complete”.**

Mentor Information

Primary Mentor First Name, Last Name, Email Address, Phone Number, Title, Institution

Mentor Invite

All Winn CDA awardees must designate at least one 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 mentor will receive an email with an invite to complete the recommendation by submitting a
- Biosketch and a Letter of Support.
- 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.
- You will be notified by email when the mentor Accepts or Declines the recommendation. *****Note: This task will appear with a 'half full circle', which means that the request was successfully sent to the mentor. It <u>does not mean</u> the mentor uploaded their required documents.*****

To resend or withdraw the request, click the ellipsis (…) near the mentor’s name and email and select the appropriate option from the drop-down list as shown below.

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”**.

<u>Form for "Mentor Invite"</u>

Mentor Recommendation

*Mentorship Model and Mentor Roles and Responsibilities: Mentors must hold an MD, DO, MD/PhD, or DO/PhD. Mentors from an academic institution must hold a position as an associate or full professor. Mentors are expected to be established Clinical Investigators with an active clinical trial that the scholar can work on during the two-year program period. Note: submission of a copy of the protocol is a required component of the application. **Research projects must meet the NIH Clinical Trial Definition - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

Mentorship is a critical aspect of the Winn CDA program. It is estimated that clinical trial activities will comprise 75% of a mentor’s activities. Mentors will engage scholars in the active conduct of an existing clinical trial and

provide exposure to all aspects of CT administration and implementation. The remaining 25% of the mentor's focus will be on career, personal, and professional mentoring. The mentor will provide guidance on career and professional development, with a particular focus on challenges, opportunities, and strategies for URM researchers. Through this process, the mentor will share personal experiences that have influenced their career pathway.

The structure of the mentorship plan should be designed based on an estimated time commitment of 75% clinical trial research mentoring and 25% career (e.g., personal and professional) development mentoring. Minimum requirements for a mentorship plan include at least 4 meetings per month, of which 3 shall be in-person or live virtual meetings related to clinical trial research activities. The Winn CDA program staff will provide mentorship support and resources for the mentor. Quarterly group mentor meetings are encouraged, where mentors may share experiences, concerns, challenges, and best practices. The Winn CDA program staff will monitor the mentorship plan and collect quarterly mentor status reports.

The Mentor honorarium/stipend is set at $4,800 per year and is tied to career/personal/professional development mentoring. Honoraria/stipends will be disbursed annually, and benchmarks will include the fulfillment of responsibilities articulated in the mentorship plan. There will be a formal mentor onboarding process and mentors will participate in a mentor orientation session.

Mentors will have to upload the following:

- **Mentor Biosketch**
- **Mentor Letter of Support**
- **Mentorship Plan**

Project Timeline Form

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 any special characters.**

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

Personal Statement Form

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 increasing diversity in clinical trials.
- 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 will 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 has been or will be submitted. If none, please indicate N/A.

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

Budget

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 6-day intensive obert A. Winn iversity in Clinical Trials esi n an Implementation of Clinical Trials Workshop in partnership ith the American Association for Cancer esearch Winn-AAC ICT Workshop in early November; the obert A. Winn iversity in Clinical Trials 2- r Community-oriente Clinical Trialist Trainin Winn COCT Trainin , inclu in bi-weekly 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:

- Total Award: 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.
- Salary support: The budget guideline is to allocate $100,000 per year to support 40% of the Scholar's time, although institutions may allocate the full $120,000 to salary support to protect the Scholar's time.
- Indirect costs: Up to $10,000 of the award, per year, may be applied to overhead or facilities and administrative costs of the applicant's institution in administering the research project.
- Discretionary funds: Remaining funds should be specifically allotted to essential needs related to conducting the study such as a portion of a research assistant/navigator salary or travel expenses.

*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 trainings and the Winn CDA Annual Convening is required and costs will be covered by the program. Meeting requirements include:

- Day 1 Virtual Orientation
- Winn-AACR DICT Workshop (4.5-day intensive, in person training November 15th -20th in La Jolla, CA)
- Bi-weekly Winn CDA Scholars Forum – every other Friday 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 (i.e., 34 of 43). Live virtual participation for a minimum of 2-hours is required for attendance to be recognized. Scholars are required to submit a post-webinar survey after each forum.
- Two 1.5 day Annual Convenings in early November at the end of program years 1 and 2 (Dates and locations TBD)

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

Use this file naming convention:[last name first name Budget] (i.e., Smith John Budget)
*Please do not use any special characters.**

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

Applicant's Biosketch

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 any special characters.**

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

Research Strategy

Please describe the research strategy of the clinical trial you will be working on. 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:
   - I. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - II. Explain how the proposed project will improve scientific knowledge, technical capability, and/or critical practice in one or more broad fields.
   - III. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will change if the proposed aims are achieved.

2. Innovation:
   - I. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - II. 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.
   - III. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. Approach:
   - I. 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.
   - II. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
   - III. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. Appropriate detail and/or documentation in the Supporting Documentation section must be included to assure a reviewer that the applicant's project is feasible in the time frame of the grant. Examples include: a letter confirming access to an experimental therapy or an approval letter from a CTEP or a cooperative group. NOTE: Applicants may send supporting letters regarding feasibility (e.g., proof of receipt of drug from a company, IRB approval, etc.) to winncda@vcu.edu until **May 19, 2023**.
   - IV. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
   - V. Clearly state the applicant's role in the project (e.g., writing of the protocol, 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.
   - VI. 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

I. Discuss your goals for accruing patients from groups underrepresented in medicine (URM).
II. Describe your proposed strategy and methodology for enrolling and retaining URM patients.
III. 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 any special characters.**

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

Cited References (required)

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 any special characters.**

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

Institutional Letter of Support from Department Chair or Dean

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 Winn CDA activities) and commitment of institutional resources needed to perform the proposed research. This letter must be signed and on official letterhead.

If the letter is not signed and not printed on official letterhead, Winn CDA will reject and return the application.

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 any special characters.

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

Clinical Protocol (required)

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

Protocol Title

Upload an Executive Summary for the Protocol.

Click here for the Executive Summary instructions. **Click here** for the Executive Summary template.

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

Supporting Documentation (optional)

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 any special characters.

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

Institutional Approval

The head of your institution's Office of Sponsored Research, the authorized official representing the sponsoring institution, must approve the completed application before submission by completing the "Institutional Approval" task. The task will not be available until all the required application tasks have been completed.

- 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' however, which means that the request was successfully sent to the institution. It does not mean 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 the deadline. An email notification will be sent to the applicant confirming that the task has been completed.

- You will not be able to submit the application until this task is submitted.
- Once the Institution Approver has submitted the task, return to this section and click "**Mark as Complete**".

Institutional Approval Form

Official name of your institution, Institution Address, Institution City, Institution State, Institution Zip Code, EIN# or Tax ID, First Name of Institution Approver, Last Name of Institution Approver, Email Address of Institution Approver, Phone Number of Institution Approver

By providing my signature below, as Authorized Official from the applicant's sponsoring institution, I have reviewed the application in full and support the applicant's submission.

Review your application

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.

Application Submission Checklist

- ☐ Applicant Information (required)
- ☐ Training, Employment and Interest (required)
- ☐ Funding/Publication and Additional Questions (required)
- ☐ Project Information (required)
- ☐ Mentor Recommendation(s) (required)
- ☐ Mentor Biosketch and Letter of Support (required)
    - o Mentor Biosketch
    - o Mentor Letter of Support
    - ○ Mentor Plan
- ☐ Project Timeline Form (required)
- ☐ Personal Statement Form (required)
- ☐ Budget (required)
- ☐ Applicant's Biosketch (required)
- ☐ Research Strategy (required)
- ☐ Cited References (required)
- ☐ Institutional Letter of Support from Department Chair or Dean (required)
- ☐ Clinical Protocol - Executive Summary (required)
- ☐ Supporting Documentation (optional)
- ☐ Institution Approval (required)
- ☐ Review and Submit (required)

Appendix A. Helpful Tips for Using the Application Portal

Navigating the Application

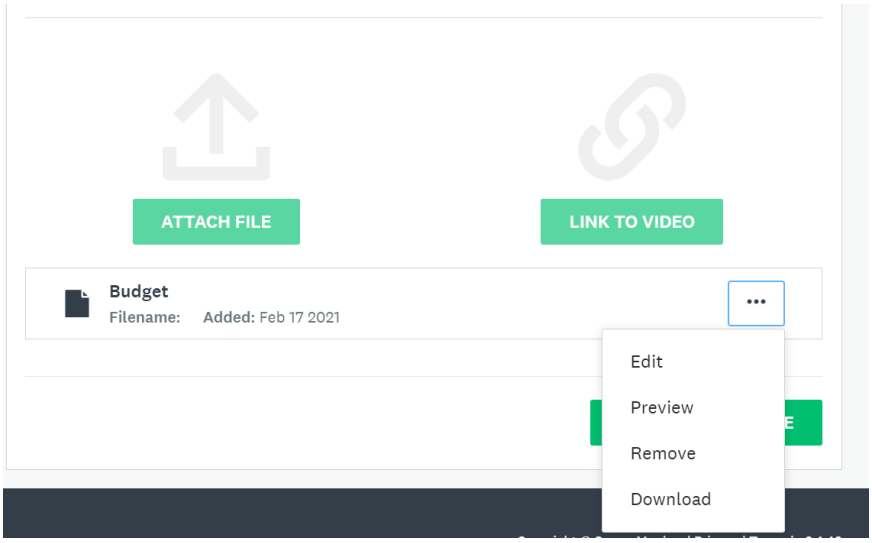
- Click "Save and Continue Editing" at the bottom of the page as you go through the application or "Next" to continue to the next section.
- When finished with a particular task (e.g., Project Information), click "Mark as Complete" at the bottom of the page to validate task completion.
- If you need 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.
    - **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.

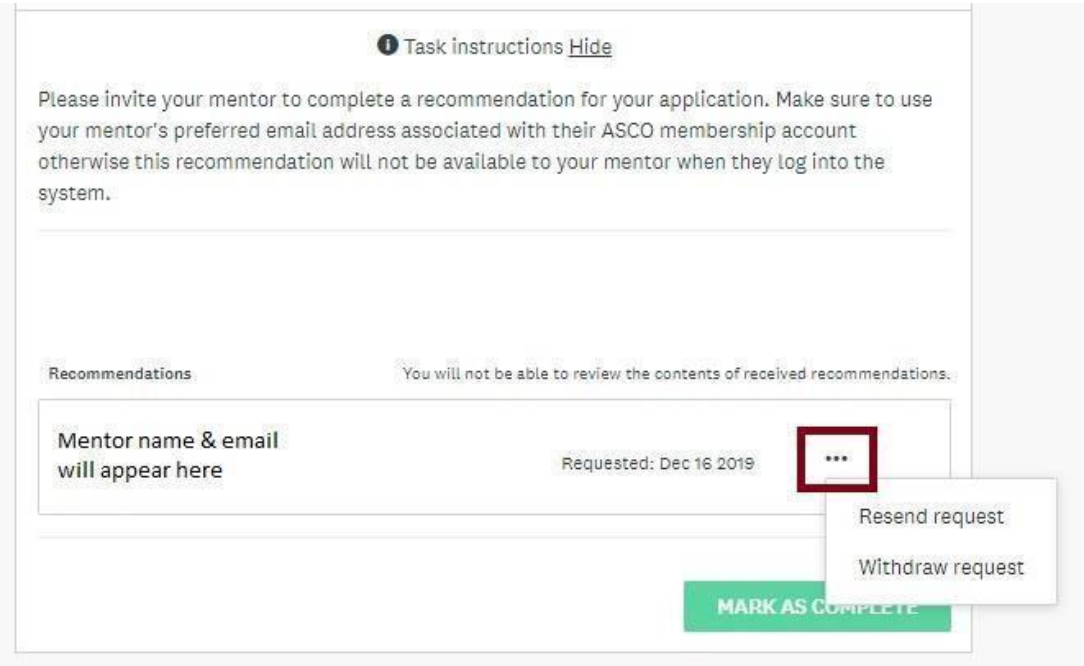
Uploading a Document

- 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.



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

Name:

Current Sources of Funding Please list all current sources of funding including: Name of funder, Amount, Funding Period, Renewable, and Brief Summary/Description						
Funding Source Name: Please enter in the name of your funding source	**Amount:** Please enter in the dollar amount of funding from this source	**Funding Period:** Please enter the funding period (Use format MM/YY - MM/YY)	**Percentage of time spent:**	**Is the funding renewable ?** Yes/No	**Are you the Principal Investigator ?** Yes/No	**Please describe how this funding supports your work. (150 words max)**

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

INSTRUCTIONS: Please enter the major milestone(s)/activity(ies) of your research project and include a description, the expected completion date, whether it is a deliverable or not, and the status. You may hover over each column heading for additional instructions. A sample is included in line 3. NOTE: If you are selected to receive an award, you will be asked to update this template and upload during each reporting period. You may insert row(s) to add milestone(s) or activity(ies). Do not delete previous entries added from your application.

Name:

Milestone/Activity	Description	Expected Completion Date	Is Deliverable	Status	Comments (Do not fill out during application.Use for progress reporting only.)
Patient Recruitment	*Recruit 10 study participants by completion date*	*31-Dec-2020*	*No*	*Not Started*	

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

Name:

BUDGET	Year 1	Year 2	Total
1. RESEARCH SUPPORT			
Scholar's Salary	$0	$0	$0
2. DISCRETIONARY FUNDING			
Assistant/ Coordinator Salary	$0	$0	$0
Supplies/ Equipment	$0	$0	$0
Travel	$0	$0	$0
	$0	$0	$0
	$0	$0	$0
	$0	$0	$0
3. INDIRECT COST			
Indirect Cost	$0	$0	$0
4. TOTAL BUDGET	$0	$0	$0

Budget Guidelines:

1. Salary Support: The budget guideline is to allocate $100,000 per year to support 40% of the Scholar's time, although institutions may allocate the full $120,000 to salary support to protect the Scholar's time.

2. Remaining funds should be allotted specifically to essential needs related to conducting the study such as a portion of a research assistant/coordinator salary, supplies, or equipment expenses.

3. Indirect costs: 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.

4. The total budget requested must be no more than $240,000 for the 2 years.

Instructions for a Biographical Sketch
Updated October 2022 – See Guide Notice NOT-OD-21-073

(located in the SF424 R&R Instructions, G.240 R&R Senior/Key Person Profile Expanded Form)

These instructions apply to Research (R), Career Development (K), Training (T), Fellowship (F), Multi project (M), and SBIR/STTR (B). Hyperlinks and URLs are only allowed when specifically noted in funding opportunity announcement (FOA) and form field instructions

Who must complete the "Biographical Sketch" section:

All senior/key personnel and other significant contributors (OSCs) must include biographical sketches (biosketches).

Format:

Use the sample format on the Biographical Sketch Format Page to prepare this section for all grant applications.

Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).

The biosketch may not exceed 5 pages per person. This 5-page limit includes the table at the top of the first page.

Attach this information as a PDF file. See the Format Attachments page.

Content:

Note that the instructions here follow the format of Biographical Sketch Format Page.

Name:

Fill in the name of the senior/key person or other significant contributor in the "Name" field of the Biosketch Format Page.

eRA Commons User Name:

If the individual is registered in the eRA Commons, fill in the eRA Commons User Name in the "eRA Commons User Name" field of the Biosketch Format Page.

The "eRA Commons User Name" field is required for the PD/PI (including career development and fellowship applicants), primary sponsors of fellowship applicants, all mentors of candidates for mentored career development awards, and candidates for diversity and reentry research supplements.

The "eRA Commons User Name" field is optional for other project personnel.

The eRA Commons User Name should match the information provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) Form in your grant application.

Position Title:

Fill in the position title of the senior/key person or other significant contributor in the "Position Title" field of the Biosketch Format Page.

Education/Training

Complete the education block. Begin with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately.

For each entry provide:

- the name and location of the institution
- the degree received (if applicable)
- the month and year of end date (or expected end date). For fellowship applicants only, also include the month and year of start date.
- the field of study (for residency entries, the field of study should reflect the area of residency training)

Following the education block, complete Sections A-D of the biographical sketch.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields, including ongoing and completed research projects from the past three years that you want to draw attention to (previously captured under Section D. Research Support).

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware. Use of hyperlinks and URLs to cite these items is not allowed.

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

Note the following additional instructions for ALL applicants/candidates:

- If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this "A. Personal Statement" section.
- Indicate whether you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application.
- Figures, tables, or graphics are not allowed.

Note the following instructions for specific subsets of applicants/candidates:

- For institutional research training, institutional career development, or research education grant applications, faculty who are not senior/key persons are encouraged, but not required, to complete the "A. Personal Statement" section.
- Applicants for dissertation research awards (e.g., R36) should, in addition to addressing the points noted above, also include a description of their career goals, their intended career trajectory, and their interest in the specific areas of research designated in the FOA.
- Candidates for research supplements to promote diversity in health-related research should, in addition to addressing the points noted above, also include a description of their general scientific achievements and/or interests, specific research objectives, and career goals. Indicate any current source(s) of educational funding.

B. Positions, Scientific Appointments and Honors

List in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full time, part-time, or voluntary (including adjunct, visiting, or honorary). High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

C. Contributions to Science

Who should complete the "Contributions to Science" section:

All senior/key persons should complete the "Contributions to Science" section except candidates for research supplements to promote diversity in health-related research who are high school students, undergraduates, and post-baccalaureates.

Format:

Briefly describe up to five of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations.

While all applicants may describe up to five contributions, graduate students and postdoctorates may wish to consider highlighting two or three they consider most significant.

Content:

For each contribution, indicate the following:

- the historical background that frames the scientific problem;

- the central finding(s);
- the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and
- your specific role in the described work.
- Figures, tables, or graphics are not allowed.

For each contribution, you may cite up to four publications or research products that are relevant to the contribution. If you are not the author of the product, indicate what your role or contribution was. Note that while you may mention manuscripts that have not yet been accepted for publication as part of your contribution, you may cite only published papers to support each contribution. Research products can include audio or video products (see the NIH Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant Application Materials); conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware. Use of hyperlinks and URLs to cite these items is not allowed.

You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required.

Descriptions of contributions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication. These contributions do not have to be related to the project proposed in this application.

***D. Scholastic Performance**

****Note that only the following types of applicants must complete this section:***

- applicants for predoctoral and postdoctoral fellowships
- applicants to dissertation research grants (e.g., R36)
- candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels

Scholastic Performance

Predoctoral applicants/candidates (including undergraduates and post-baccalaureates): List by institution and year **all** undergraduate and graduate courses, with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

Postdoctoral applicants: List by institution and year **all** graduate scientific and/or professional courses with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Hunt, Morgan Casey

eRA COMMONS USER NAME (credential, e.g., agency login): huntmc1

POSITION TITLE: Associate Professor of Psychology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	BS	05/2003	Psychology
University of Vermont	PHD	05/2009	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/2013	Public Health and Epidemiology

A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with substance use disorders. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of substance use disorders. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to older people with substance use disorders, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2015-2016, my career was disrupted due to family obligations. However, upon returning to the field, I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have the expertise, leadership, training, expertise, and motivation necessary to successfully carry out the proposed research project.

Ongoing and recently completed projects that I would like to highlight include:

R01 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older people with substance use disorders

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression, and substance use among older adults

R21 AA998075
Hunt (PI)
01/01/19-12/31/21
Community-based intervention for alcohol abuse

Citations:

1. Merryle, R.J. & **Hunt, M.C.** (2015). Independent living, physical disability and substance use among older adults. Psychology and Aging, 23(4), 10-22.
2. **Hunt, M.C.**, Jensen, J.L. & Crenshaw, W. (2018). Substance use and mental health among community-dwelling older adults. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. **Hunt, M.C.**, Wiechelt, S.A. & Merryle, R. (2019). Predicting the substance use treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292
4. Merryle, R. & **Hunt, M.C.** (2020). Randomized clinical trial of cotinine in older people with nicotine use disorder. Age and Aging, 38(2), 9-23. PMCID: PMC9002364

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2021– Present	Associate Professor, Department of Psychology, Washington University, St. Louis, MO
2020 – Present	Adjunct Professor, McGill University Department of Psychology, Montreal, Quebec, Canada
2018 – Present	NIH Risk, Adult Substance Use Disorder Study Section, member
2015 – 2017	Consultant, Coastal Psychological Services, San Francisco, CA
2014 – 2021	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2014 – 2015	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2014 – Present	Board of Advisors, Senior Services of Eastern Missouri
2013 – 2014	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2011 – Present	Associate Editor, Psychology and Aging
2009 – Present	Member, American Geriatrics Society
2009 – Present	Member, Gerontological Society of America
2009 – 2013	Fellow, Intramural Research Program, National Institute on Drug Abuse, Baltimore, MD
2006 – Present	Member, American Psychological Association

Honors

2020	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society
2019	Excellence in Teaching, Washington University, St. Louis, MO
2018	Outstanding Young Faculty Award, Washington University, St. Louis, MO

C. Contributions to Science

1. My early publications directly addressed the fact that substance use is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging concerns about a substance use disorder. These publications document this emerging concern and guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the behavior, and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for older adults with substance use disorders and will continue to provide assistance

in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

a. Gryczynski, J., Shaft, B.M., Merryle, R., & **Hunt, M.C.** (2013). Community based participatory research with late-life substance use disorder. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
b. Shaft, B.M., **Hunt, M.C.**, Merryle, R., & Venturi, R. (2014). Policy implications of genetic transmission of alcohol and drug use in women who do not use drugs. International Journal of Drug Policy, 30(5), 46-58.
c. **Hunt, M.C.**, Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2015). Early-life family and community characteristics and late-life substance use. Journal of Applied Gerontology, 28(2),26-37.
d. **Hunt, M.C.**, Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2018). Community-based intervention strategies for reducing alcohol and drug use in older adults. Addiction, 104(9), 1436-1606. PMCID: PMC9000292

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older people with substance use disorders and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of substance use disorders and the disruptive potential of networks in substance use treatment. This body of work also discusses the prevalence of alcohol and amphetamine use in older adults and how networking approaches can be used to mitigate the effects of these disorders.
    a. **Hunt, M.C.**, Merryle, R. & Jensen, J.L. (2015). The effect of social support networks on morbidity among older adults with substance use disorders. Journal of the American Geriatrics Society, 57(4), 15-23.
    b. **Hunt, M.C.**, Pour, B., Marks, A.E., Merryle, R. & Jensen, J.L. (2018). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
    c. Merryle, R. & **Hunt, M.C.** (2020). Randomized clinical trial of cotinine in older people with nicotine use disorders. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364

3. Methadone maintenance has been used to treat people with substance use disorder for many years, but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Older adults were shown, in carefully constructed ethnographic studies, to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.

    a. **Hunt, M.C.** & Jensen, J.L. (2013). Morbidity among older adults with substance use disorders. Journal of the Geriatrics, 60(4), 45-61.
    b. **Hunt, M.C.** & Pour, B. (2015). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
    c. Merryle, R. & **Hunt, M.C.** (2018). The use of various nicotine delivery systems by older people with nicotine use disorder. Journal of Aging, 54(1), 24-41. PMCID: PMC9112304
    d. **Hunt, M.C.**, Jensen, J.L. & Merryle, R. (2020). Aging and substance use disorder: ethnographic profiles of older people with substance use disorder. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1ICifFFV4VYQZE/bibliography/public/

Additional Instructions for Multi-Project:

Each Senior/Key Person, including the PD/PI, is allowed one biosketch for the entire application. If an individual will participate on multiple components, attach the biosketch to any single component.

Protocol Summary

Title:	<Full title>
Study Description:	*Provide a short description of the protocol, including a brief statement of the study hypothesis. This should be only a few sentences in length. A detailed schematic describing all visits and a schedule of assessments should be included in the* ***Schema and Schedule of Activities, Sections 1.2 and 1.3,*** *respectively.*
Objectives:	*Include the primary and secondary objectives. These objectives should be the same as the objectives contained in the body of the protocol. These align with Primary Purpose in clinicaltrials.gov*[1]*.* <Primary Objective: Secondary Objectives: >
Endpoints:	*Include the primary endpoint and secondary endpoints. These endpoints should be the same as the endpoints contained in the body of the protocol. These align with Outcome Measures in clinicaltrials.gov.* <Primary Endpoint: Secondary Endpoints: >
Study Population:	*Specify the sample size, gender, age, demographic group, general health status, and geographic location.*
Phase:	<2 or 3 or N/A> *Phase applies to drugs and biologics*[2].
Description of Sites/Facilities Enrolling Participants:	*Provide a brief description of planned facilities/participating sites enrolling participants. Indicate general number (quantity) of sites only and if the study is intended to include sites outside of the United States.*
Description of Study Intervention:	*Describe the study intervention. If the study intervention is a drug or biologic, include dose and route of administration. For devices, provide a description of each important component, ingredient, property and the principle of operation of the device.*
Study Duration:	*Estimated time (in months) from when the study opens to enrollment until completion of data analyses.*
Participant Duration:	*Time (e.g., in months) it will take for each individual participant to complete all participant visits.*

[1] From ClinicalTrials.gov Protocol Data Element Definitions available at: *https://prsinfo.clinicaltrials.gov/definitions.html*. Accessed March 2017.

[2] From 21 CFR 312.21 "Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects… Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects."

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

Protocol Summary

Title

Study Description

Objectives:
Primary Objective

Secondary Objectives

Endpoints:
Primary Endpoint

Secondary Endpoints

Study Population

Phase

Description of Sites/Facilities Enrolling Participants

Description of Study Intervention

Study Duration

Participant Duration