GUIDELINES FOR INTERNAL UAB MWCCS PILOT FUNDING APPLICATIONS



The Multicenter AIDS Cohort (MACS)/Women's Interagency HIV Study (WIHS) combined cohort study (MWCCS) is a collaborative research effort that aims to explore and understand the impact that chronic health conditions have on individuals with HIV and those who are at risk of acquiring HIV. The decade-long work of the MWCCS has helped to improve the diagnosis, treatment and prevention of HIV/AIDS. The objective of this plot funding internal grant application is to fund HIV-related co-morbidity scientific research projects that will incorporate the utilization of MWCCS resources (i.e. database and biological samples). The idea behind this strategy is to develop a highly integrative HIV research environment with the UAB/UMMC MWCCS research team. Priority will be given to those projects that have the potential of obtaining future extramural funding. We anticipate funding two applications up to \$30,000 each. Statistical and data management support will be provided by the UAB/UMMC MWCCS site. For information about MWCCS, go to: https://statepi.jhsph.edu/mwccs/

Eligibility Criteria

Faculty, fellows, and post-docs at the University of Alabama at Birmingham or the University of Mississippi Medical Center (UMMC; including join UMMC/VA appointments) or affiliated with UAB or UMMC are eligible to apply. Junior investigators developing a new and novel idea in an HIV-related field not related to current R- or U-funding that they are PI of are given preference during the review process. Established investigators who are new to HIV research (i.e., no prior HIV/AIDS funding of any type) and are looking to explore the field of HIV/AIDS are encouraged and eligible to apply. **Per NIH guidance, clinical trials are not allowed. To determine the difference between clinical studies and clinical trials, please refer to https://grants.nih.gov/policy/clinical-trials/definition.htm.**

Submission of Applications

Timeline

- o RFA Released: December 4, 2020
- Deadline for 2-page Concept: December 21, 2020
- o Full Application Applicants Announced: January 1, 2021
- Deadline for Full Applications: February 25, 2021
- Awards Announced: Week of March 15, 2021
- o Funding Start: April 1, 2021
- Funding End: March 31, 2022 (i.e. MWCCS Pilot Grants are made for one year)

Concept Proposals

An electronic copy of the proposal should be submitted via the RED-ASSIST platform (https://redcap.dom.uab.edu/surveys/?s=XKRYLHKE34) as a single file in PDF format. Please name the file as "2021 MWCCS Pilot Concept Proposal-[Name]." Proposal cover letters should be addressed to Mirjam-Colette Kempf (UAB MWCCS PI), Jodie Dionne-Odom (UAB MWCCS PI), Deborah Konkle-Parker (UMMC MWCCS PI), Venetra McKinney (UMMC MWCCS PD) and Zenoria Causey Pruitt (UAB MWCCS PD) and be signed by the principal investigator(s), department chair and/or the appropriate university official(s). The project description should be no more than 2-pages and include the following:

Project Description

Outline the hypotheses, specific aims, brief preliminary data (if any), and brief research design. As the criteria for funding are primarily based upon the scientific merit, investigator, significance, approach, and innovation,

concepts should address these topic areas. Describe how MWCCS resources will be utilized in your research hypotheses and specific aims.

Combined Significance and Innovation Section

Briefly explain the importance/significance of the proposed project in the context of biomedical research that is promoted by the NHLBI or other NIH institutes engaged in HIV research. Describe the innovative nature of the proposal and how the proposed research will advance the field of HIV or one of the MWCCS's <u>United Scientific Agenda aims</u>. Note the specific NIH funding sources to be targeted with the results from this study.

Eligibility/Team Building Component (no more than one-half page)

The integration of investigators with experienced UAB/UMMC MWCCS researchers at various levels is recommended to advance all pilot projects within the context of a team-building approach. Co-investigators should include senior, junior or early stage investigators constituting research teams.

Investigators should clearly state how their proposed research will impact the UAB or UMMC research environment, improve the site's research infrastructure (e.g. provision of assays, facilitating access to methods, improved knowledge, enhanced ability to apply for common funding), utilize MWCCS resources and thereby facilitate future HIV research by other UAB or UMMC investigators.

Biosketches (Include one for each investigator)

All applicants and collaborators should submit NIH biosketches with personal statements adapted to describe defined roles on the project. Use the NIH form. https://grants.nih.gov/grants/forms/biosketch.htm

Researchers whose proposals are selected for the full proposal competition phase will be notified by email.

Please note the following administrative requirements: Page limitations indicated throughout the application will be strictly enforced. Applications should reflect NIH font sizes only, minimum size 11.0 Arial, Helvetica, Palatino or Georgia. Please attach a copy of the entire summary statement or original review comments from other funding sources for proposed projects that have been reviewed previously. In addition, include a brief description of the changes you have made to your submission based on prior reviewer comments or suggestions (1 page maximum). Biosketches are required from all investigators and letters of support are required from all consultants. Application who do not adhere to these guidelines will not be considered.

Full Applications

Those invited to submit a full proposal will receive a unique RED-ASSIST link to submit their proposal as a single file **in PDF format.** Please name the file as "2021 MWCCS Pilot Full Proposal-[Name]." Proposal cover letters should be addressed to Mirjam-Colette Kempf (UAB MWCCS Co-PI), Jodie Dionne-Odom (UAB MWCCS Co-PI), Deborah Konkle-Parker (UMMC MWCCS PI), Venetra McKinney (UMMC MWCCS PD) and Zenoria Causey Pruitt (UAB MWCCS PD) and be signed by the principal investigator(s), department chair and/or the appropriate university official(s). The full proposal will be on the forms used commonly for NIH grant applications (PHS 398 forms) and should follow a modified NIH investigator initiated grant application (R01) format.

For detailed instructions on how to fill out the forms see: https://grants.nih.gov/grants/funding/phs398/.pdf with the following modifications. The Research Plan (Specific Aims through Approach) is limited to 4 pages (Bibliography and References Cited sections do not count toward the page limit). No appendices. Or Targeted/Planned Enrollment Tables are allowed. Applications must be in English. *Please note that applications that do not adhere to the instructions will not be considered.*

The Full Proposal should include (in this order in a single Adobe Portable Document Format (PDF) file):

- 1. Complete budget and justification: (Download: MS Word or PDF)
- 2. Research Plan (Maximum 4 pages for **a-d** below). Use PHS 398 Continuation Format pages (Download: MS Word or PDF).
 - a. Specific Aims (suggested length ½ page)
 - b. Significance (suggested length 1 page)

- c. Innovation (suggested length ½ page)
- d. Approach (suggested length 2 pages)
- 3. Description of the Research Environment (suggested length ½ page). Use PHS 398 Continuation Format pages (Download: MS Word or PDF).
- 4. Bibliography and References cited (as needed) Use PHS 398 Continuation Format pages (Download: MS Word or PDF).
- 5. Protection of Human Subjects (if applicable; maximum 1 page). Use PHS 398 Continuation Format pages (Download: MS Word or PDF).
- 6. Vertebrate Animals (if applicable; maximum 1 page). Use PHS 398 Continuation Format pages (Download: MS Word or PDF).
- 7. Letters of Support (letters of support from collaborators essential to the proposed project must accompany the application).

Budget Development Guidelines and Restrictions (NIH budget form (Form page 5) with justification)

- Maximum direct costs will be specified at the time of the announcement; Indirect costs are allowed at the UAB rate. Awards are one year in length. One no-cost extension may be requested at the end of the first year budget period <u>only</u>.
- Salary support is limited to 10% for the PI, unless special permission is received.
- Budgeting for travel to other conferences to present project research results is allowable (travel budget limited to no more than \$2000). Travel must be approved by MWCCS site PI.
- Awardees who have support from K awards should discuss eligibility issues with their program officers and with institutional officials as eligibility may vary by NIH sponsor for the K award and institutional policies. The staff of this mechanism is not able to determine eligibility for K awardees.
- All costs must conform to the NIH Grants Policy Statement (GPS) and applicable U.S. Office of Management and Budget OMB circulars for necessity and reasonability, allocability, conformance and consistency, as well as allowability. Please follow the link below to section 7.2 cost principles section of the NIH Grants Policy Statement.

Review Criteria

A Scientific Selection Committee (SSC) consisting of members from the UAB/UMMC investigators and/or members of the MWCCS External Advisory Board will review the applications. Criteria for selection are primarily based upon the scientific merit, investigative team, significance, approach, and innovation. Specifically, the project will be evaluated for its significance and its aligned with the strategic interests of the NHLBI MWCCS cohort specific aims. Applications must clearly describe a vision and the feasibility of the approach. Applications based on a high degree of innovation are preferred. The use of MWCSS database and resources is required. Applications will be reviewed by the MWCCS biostatistics and analysis team as part of the review process.

Award Details

Pre-Award Approvals

Funding will be awarded from the UAB MWCCS Finance Office. All questions regarding the awarding of funding should be directed to the contact listed in the notice of award. Prior to the awarding of funding, the following information must be provided, if applicable:

Animal Care and Institutional Review Board approvals, if applicable, must be obtained prior to receipt of
an award, but are not required to submit an application. Prior to funding, a copy of all <u>Institutional</u>
<u>Biohazard</u>, Animal Care and Institutional Review Board (IRB) approvals must be forwarded to the postaward administrator. Prior to receipt of an award involving human subjects, IRB approval from all
participating sites and human subjects training certification for all key personnel will be required.

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- A concept sheet must be approved by the MWCCS Executive Committee prior to award.
- For more information about human subjects approval, see: https://www.his.gov/ohrp/ and https://www.niaid.nih.gov/grants-contracts/human-subjects.
- For more information on animal care approvals, see: https://grants.nih.gov/grants/olaw/olaw.htm and https://www.niaid.nih.gov/research/grants-animals-research.

Post-Award Requirements

- Applicants chosen for funding will be expected to present the details of their study to the UAB/UMMC
 monthly MWCCS Research Roundtable Meeting for review of the study objectives. This will provide an
 opportunity to identify additional synergies within MWCCS, explore other means of support and
 recommendations to enhance the study. Other presentations, including a 'research in progress talk'
 (midway) and at the end of the funding period may be requested.
- Awardees may be required to attend mentoring activities, complete an initial Mentoring Agreement and
 create a mentoring plan with their mentors. Activities may also include workshops, trainings or meeting
 with advisors to facilitate faculty development. If an applicant is unable to select a mentor, UAB MWCCS
 leadership will work with awardees to identify mentors during the application process.
- Applications may be partially funded across two MWCCS budget periods in partial amounts. Remainder
 of funding will be awarded upon satisfactory progress towards the proposed aims and evidence of
 appropriate spending. Awarded funds should be expended within a 12 month period beginning with the
 date of the award. Funds can be extended for a 6 month period with justification through a no-cost
 extension.
- Awardees will be required to submit yearly progress reports**. Awardees will be tracked after the award ends to monitor productivity (abstracts, publications, grants).
- Support from this mechanism must be <u>acknowledged</u> in all publications and presentations. Visit the MWCCS website for language describing the appropriate acknowledgement of this funding source.
- If for any reason the awardee is unable to fulfill the requirements or adhere to the policies of the award, at the discretion of the funding mechanism leadership, the award may be revoked immediately.

**All recipients of MWCCS funding are obliged to provide information, not limited to, progress reports or final performance reports, as requested by the MWCCS Administrative Core. Failure to provide such information in a prompt and timely manner may result in the immediate termination of the grant and will preclude the grantee from applying for future MWCCS funding opportunities.

For more information on the MWCCS study, visit https://statepi.jhsph.edu/mwccs/

For information on the UAB-UMMC MWCCS research site, visit https://sites.uab.edu/mwccs/

For questions at UAB, please contact Mirjam-Colette Kempf at mkempf@uab.edu, Jodie Dionne-Odom at jdionne@uabmc.edu or Zenoria Causey Pruitt at zcausey@uabmc.edu.

For questions at UMMC, please contact Deborah Konkle-Parker at dkparker@umc.edu and Venetra McKinney at vmckinney@umc.edu.