Frequently Asked Questions (FAQs) for PAR-20-179, PAR-20-180, NOT-OD-20-150, and NOT-OD-20-151

PAR-20-179:
Advancing Research to Develop Improved Measures and Methods for Understanding Multimorbidity

PAR-20-180:
Identifying Innovative Mechanisms or Interventions that Target Multimorbidity and Its Consequences

NOT-OD-20-150:
Notice of ORWH's and NICHD's Participation in PAR-20-179

NOT-OD-20-151:
Notice of ORWH's and NICHD's Participation in PAR-20-180

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INTRODUCTION

The Funding Opportunity Announcement (FOA) PAR-20-179 invites applications that seek to improve the availability, quality, and utility of data and measures that capture multimorbidity or multiple chronic conditions (MCCs) and the methods for analyzing multimorbidity data. Research supported by this initiative should be designed to develop improved measures and methods for understanding multimorbidity, including but not limited to measures/tools to support basic mechanistic discovery of shared MCC pathways and identification and initial evaluation of MCC shared signatures.

The FOA PAR-20-180 invites applications that seek to support the identification of shared mechanisms and development of innovative interventions to address MCCs and its consequences. Intervention research supported by this initiative should be designed to study: (1) mechanisms or pathways that prevent MCCs, including the identification of early biomarkers, behavioral pathways, and individual and contextual risk factors and interactions that contribute to the development of common MCCs; (2) targeted therapies and management, including self-management, of MCCs to delay progression and prevent onset of new diseases; and (3) innovative health care partnership models for managing or treating MCCs.

To date, there are 13 NIH Institutes, Centers, and Offices participating in these two PARs (PAR-20-179 and PAR-20-180). Furthermore, two NIH Notices (NOT-OD-20-150 and NOT-OD-20-151) announcing ORWH’s (the Office of Research on Women’s Health) and NICHD’s (Eunice Kennedy Shriver National Institute of Child Health and Human Development) participation in these two PARs were published on July 29, 2020. It is important to note that most NIH Offices (ODP, OBSSR, ORWH, etc.) do not hold or manage grants. However, these Offices may consider providing co-funding support for grants that the participating Institutes and Centers decide to fund.

All investigators whose research interests align with these FOAs and Notices are highly encouraged to communicate directly with the NIH Scientific/Research Contacts listed at the bottom of the FOAs and Notices (PAR-20-179, PAR-20-180, NOT-OD-20-150 and NOT-OD-20-151) to discuss their research ideas and specific aims prior to submitting applications. The Scientific/Research Contacts are named in each FOA under Section VII. Agency Contacts; while the Scientific/Research Contacts for ORWH and NICHD are listed in NOT-OD-20-150 and NOT-OD-20-151.

The frequently asked questions listed below address general questions from prospective investigators in the field, as well as common FOA questions. This document also includes questions that were submitted during the technical assistance webinar for these FOAs. A recording of this webinar and the presentation slides can be found on the ODP website (prevention.nih.gov/MultimorbidityWebinar).
APPLICATION SUBMISSION

Q1. When are applications due?

A1. For non-AIDS applications: October 5, 2020 is the first standard due date for non-AIDS applications submitted to either PAR-20-179 or PAR-20-180. Standard dates apply for all types of non-AIDS applications allowed for these funding opportunity announcements (FOAs).

For AIDS and AIDS-related applications: January 2, 2021 is the first AIDS application due date for AIDS and AIDS-related applications submitted to either PAR-20-179 or PAR-20-180. Standard AIDS dates apply for all types of AIDS and AIDS-related applications allowed for these FOAs.

All applications (non-AIDS, AIDS, and AIDS-related) must be submitted by 5:00 PM local time of the applicant organization.

Q2. Am I required to submit a letter of intent?

A2. Applicants are not required to submit a letter of intent.

Q3. Does the application have a page limit?

A3. Yes. All page limitations described in the SF424 Application Guide for each PAR and the Table of Page Limits must be followed.

Q4. How should I submit my application?


Q5. Where can I find the slides and webinar recording from the technical assistance webinar for these two FOAs?

A5. Staff from the NIH Office of Disease Prevention (ODP) and the participating NIH Institutes and Centers conducted a technical assistance webinar on Tuesday, September 1, 2020 for prospective applicants interested in these two FOAs. NIH Notice NOT-OD-20-160 (Notice of Technical Assistance Webinar for Two NIH Multimorbidity FOAs - PAR-20-179 and PAR-20-180) was published on August 13, 2020. A recording of this webinar and the presentation slides can be found on the ODP website (prevention.nih.gov/MultimorbidityWebinar).

Q6. Are foreign institutions eligible to apply?
A6. Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply. Foreign components, as defined in the NIH Grants Policy Statement, are allowed.

Q7. Are applications with multiple Principal Investigators (PIs) permitted?

A7. Yes. Institutions/Organizations proposing multiple Program Directors/Principal Investigators (PDs/PIs) are encouraged to review the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

Q8. Can an organization submit more than one application to each FOA?

A8. Yes. Applicant organizations may submit more than one application, provided that each application is scientifically distinct. The NIH will not accept duplicate or highly overlapping applications under review at the same time.

Q9. When and how do I apply for co-funding from participating NIH Offices (e.g., ODP, OBSSR, ORWH, etc.)?

A9. Applicants do not directly apply for co-funding to the participating NIH Offices. IC program staff may request co-funding for meritorious applications that ICs are interested in funding.

Q10. Can potential applicants request a completed application for a successfully-funded grant from either of these PARs?

A10. Since these PARs are new, there is no track record of funded grants. In addition, the NIH only releases grant applications from successful grants through the Freedom of Information Act request process. However, the NIH RePORTER website does provide some details of funded applications that might be of interest to potential applicants. NIH RePORTER is an electronic tool that allows users to search a database of NIH-funded research projects and access publications and patents resulting from NIH funding.

RESEARCH OBJECTIVES AND SCOPE

Q11. How can I determine whether my research topic is a better fit for PAR-20-179 or PAR-20-180?

A11: Reviewing the topics of interest may be helpful to decide between the two PARs. If you are proposing to develop and test an intervention for multiple chronic conditions, then PAR-20-180 is most appropriate. If you are proposing mechanistic studies (other than tool development) on
multiple chronic conditions, then PAR-20-180 is most appropriate. For other studies that relate to measurement or tool development for multiple chronic conditions, then PAR-20-179 is most appropriate.

Q12. If my research project is relevant to more than one NIH IC, what information should I use to determine which IC is the best to receive my application?

A12. Applicants whose research may be relevant to more than one NIH IC are highly encouraged to discuss potential research aims with the Scientific/Research Contacts at participating ICs well in advance of the application deadline to ensure overall fit of the proposed research with programmatic priorities, as stated in the FOAs (see Scientific/Research Contacts statement above). The Contacts are the most appropriate individuals to help applicants identify alternative FOAs if it is determined that the applicant’s research goals are not well-aligned with any of the participating IC’s research priorities. The research interests and priority research areas of each participating IC are outlined in each FOA (see Part 2. Full Text of Announcement, Section I. Funding Opportunity Description).

Q13. My study encompasses multiple diseases, how do I determine to which IC to submit my application?

A13. Applicants are encouraged to reach out to one or more of the Scientific/Research Contacts from the participating ICs listed in FOAs and Notices to discuss alignment between project fit and their IC’s research priorities (see Scientific/Research Contacts statement above). Alignment with IC research priorities is important to IC funding decisions.

Q14. These FOAs state that clinical trials are optional. How is this determined?

A14. Both applications that either propose and those that do not propose clinical trial(s) will be accepted for these funding opportunities. Applicants proposing to conduct a clinical trial should review the NIH Definition of a Clinical Trial to determine whether or not you are conducting a clinical trial. It states a clinical trial is “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavior outcomes.” A decision tool is available to assist with the determination.

Q15. What does AIDS research have to do with applications submitted to PAR-20-179 or PAR-20-180?

A15. Knowledge gaps about the prevalence of comorbidities among people living with HIV exist, and several NIH ICs encourage applications to address these gaps. The research interests and priority research areas for each IC participating in PAR-20-179 and/or PAR-20-180 are outlined in each FOA (see Part 2. Full Text of Announcement, Section I. Funding Opportunity Description).
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Applicants are encouraged to reach out to one or more of the Scientific/Research Contacts from the participating ICs to discuss interest and alignment between project fit and their IC’s research priorities (see Scientific/Research Contacts statement above).

Q16. Are multimorbidity COVID-19 related studies included in this FOA? Is COVID-19 survivorship considered a possible condition?

A16. Applications addressing multimorbidity in the context of COVID-19 will be considered within scope and responsive to these two multimorbidity FOAs (PAR-20-179 and PAR-20-180). Applicants are encouraged to reach out to one or more of the Scientific/Research Contacts at the participating ICs listed in the specific FOA of interest to discuss alignment between project fit and their IC’s research priorities (see Scientific/Research Contacts statement above). Please note that there are other NIH FOAs that specifically call for COVID-19 research. This page contains a list of funding opportunities specific to COVID-19 (https://grants.nih.gov/grants/guide/COVID-Related.cfm). The NIH Guide for Grants and Contracts is NIH’s official publication of notices of grant policies, guidelines and funding opportunity announcements (FOAs). Furthermore, Scientific/Research Contacts can help applicants identify alternative FOAs that align with the any of the participating IC’s research priorities (see Scientific/Research Contacts statement above).

Q17. What types of pre-existing data do I need to have for my R01 application?

A17. Generally, feasibility and pilot data are expected for R01 applications. Special considerations might be given for Early Stage Investigators (ESIs). Applicants are strongly encouraged to reach out to one or more of the Scientific/Research Contacts from the participating ICs listed in the FOA (PAR-20-179 or PAR-20-180) to discuss potential research aims, to determine project fit with programmatic research priorities, and to gain an understanding about what data might be expected for a given study (see Scientific/Research Contacts statement above).

Q18. I lack pre-existing data, so which other FOAs should I apply to that support pilot studies on MCCs before I eventually apply to PAR-20-180 as an R01?

A18. The NIH Planning Grant Program (R34) provides support for the initial development of a clinical trial or research project, and the NIH Exploratory/Developmental Research Grant Award (R21) is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development. The NIH Guide for Grants and Contracts is NIH’s official publication of notices of grant policies, guidelines and FOAs and serves as the most appropriate place to learn more about these funding opportunities. Additionally, the Scientific/Research Contacts can help applicants identify alternative IC-specific FOAs (see Scientific/Research Contacts statement above).

Q19. If I plan to use existing data and/or data linkages in my study, do I need to already have access to the existing data when I apply, or can I wait until I get the
grant so I can use some of the R01 funding to pay for gaining access and/or linking datasets?

A19. Ideally, applicants should demonstrate current access to data. Including a plan for obtaining access to data and requesting funding to pay for such access might be deemed acceptable. Applicants may reach out to one or more of the Scientific/Research Contacts from the participating ICs listed in the FOA of interest (PAR-20-179 or PAR-20-180) to receive consultation about this matter (see Scientific/Research Contacts statement above).

Q20. I am interested in multi-morbidities and not all the ICs covering the conditions I am investigating are participating in the FOA, for example the National Eye Institute is not participating. How would this impact my application?

A20. The research interests and priority research areas of each participating IC are outlined in each FOA (see Part 2. Full Text of Announcement, Section I. Funding Opportunity Description). You are encouraged to reach out to one or more of the Scientific/Research Contacts from the participating ICs to discuss interest, potential impact, as well as alignment between project fit and their IC’s research priorities (see Scientific/Research Contacts statement above).

APPLICATION REVIEW

Q21. Where will my application be reviewed?

A21. Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review (CSR), in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

Q22. I am currently funded to investigate methods to evaluate multiple conditions separately, and some of these currently studied conditions will be grouped into one data base study. What criteria will be used to evaluate the application for “overlap” with current ongoing studies?

A22. All applicants are encouraged to submit applications that are scientifically distinct with minimal overlap to other grants that are currently funded. In this case, it would be beneficial to discuss the level of potential overlap and its potential impact on the scientific review process with the Scientific/Research Contact(s) from the participating IC(s) of interest prior to applying (see Scientific/Research Contacts statement above). The review criteria are outlined in each FOA in Section V. Application Review Information.
Q23. What if I apply to one IC and then after the first scientific review opt to submit to another IC? Would that be considered a new application or a resubmission?

A23. Several factors are used to determine whether an application is considered a new application or a resubmission, and the Scientific/Research Contacts listed in each FOA are the most appropriate individuals to contact regarding this (see Scientific/Research Contacts statement above). In this case, it is very important to have a discussion with Scientific/Research Contact from the “new” IC. Refer to the OER Glossary and the SF424 (R&R) Application Guide for details about application types.

Q24. What factors determine what study panel will review my application?

A24. All grant applications submitted to the NIH go to the Division of Receipt and Referral (DRR) within the CSR. For more information on the Receipt and Referral process, see CSR: Submission and Assignment Process. Prior to submitting your application, questions regarding the scientific review process can be discussed with the Scientific/Research Contact(s) from the participating IC(s) (see Scientific/Research Contacts statement above) or with a Scientific Review Officer from CSR.

Q25. Is it best to request a particular study section? How do I ensure that my application is reviewed by a panel with appropriate expertise?

A25. Applications are assigned for review based on relevance of that application to the guidelines of an individual study section as well as administrative requirements such as pre-determined review clustering agreements. NIH will consider all assignment requests. However, it is not always possible to assign an application to the requested study section. The Assisted Referral Tool (ART) was developed by the CSR to recommend potentially appropriate study sections. The information you provide ART is only used to recommend study sections; recommendations made by ART are solely for the benefit of the user and there is no guarantee that your application will be assigned to one of the study sections identified by ART.

Q26. There are many potential disease combinations to be covered in the applications and some may not investigate the same conditions. For example, investigating rheumatic disease with depression versus investigating cancer with oral diseases. Will submitted applications be separated out by disease/condition and reviewed as a group, separated according to the IC(s) of interest, or will all applications be reviewed together?

A26. The DRR in the CSR assigns each application to a review group with the expertise to evaluate the scientific and technical merit of the application. For more information on the assignment
process, see: https://public.csr.nih.gov/ForApplicants/SubmissionAndAssignment/DRR/assignmentprocess. Applications submitted to these PARs will be assigned to an appropriate Scientific Review Group on the basis of established PHS referral guidelines to the appropriate IC. Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the CSR, in accordance with NIH peer review policy and procedures.

AWARD SELECTION

Q27. On what basis are applications selected for funding?

A27. Applications will be selected for funding based on scientific merit, current NIH program research priorities, and availability of funds. Applicants are highly encouraged to discuss potential research aims with the Scientific/Research Contacts from the participating ICs to determine fit with programmatic research priorities (see Scientific/Research Contacts statement above).

Q28. What is the anticipated number of awards funded under PAR-20-179 or PAR-20-180?

A28. The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Q29. Are early stage investigators less likely to receive funding as a PI for a non-profit institution?

A29. Applicants from non-profit institutions are not less likely to receive funding. Specific policies that support early stage investigators are highlighted here (https://grants.nih.gov/policy/early-investigators/index.htm).

Q30. Since my application includes participants with multiple morbidities, what is the likelihood that two different ICs would contribute funding to my application? Is there an advantage or disadvantage for a study to have a primary and secondary sponsor?

A30. There are reasons why more than one IC may contribute funding to one grant application, and the Scientific/Research Contacts listed in each FOA are the most appropriate individuals to contact regarding this (see Scientific/Research Contacts statement above). It is important to note that most NIH Offices do not hold or manage grants. Per the availability of funds, participating Offices may provide co-funding support for meritorious applications that the participating ICs decide to fund. There are no advantages or disadvantages for a study to be funded by more than one IC.
Q31. Are the applications to all ICs considered at the same importance level or are certain medical comorbidities considered of higher priority and likely to fare better?

A31. Applications will be selected for funding based on scientific merit, current NIH program research priorities, and availability of funds. The priority research areas of each participating IC are outlined in each FOA (see Part 2. Full Text of Announcement, Section I. Funding Opportunity Description). Applicants are encouraged to reach out to one or more of the Scientific/Research Contacts from the participating ICs to discuss interest, potential impact, as well as alignment between project fit and their IC’s research priorities (see Scientific/Research Contacts statement above).

RESEARCH- OR IC-SPECIFIC QUESTIONS

For questions that are specific in nature, potential applicants are encouraged to reach out and consult with the Scientific/Research Contacts that are named in the FOAs and Notices prior to submitting an application (see Scientific/Research Contacts statement above). Discussions with the contacts from each relevant IC about potential research aims can be very helpful in determining project fit and alignment with their programmatic research priorities. A few select examples of research- and IC-specific questions that were submitted prior to or during the technical assistance webinar for these PARs are included below:

- What are the top co-morbidities in older adults that are of interest to NIH?
- I am employed by a university-based medical center in the United States, and I am evaluating a pediatric HIV population with multiple morbidities at a foreign site. Are there special requirements I should be aware of regarding foreign pediatric populations and where would those requirements be listed?
- Polypharmacy is a major consequence of MCCs, and while multiple drugs are required for treating MCCs there is a potential risk of adverse drug events. Are adverse drug events from polypharmacy an area of interest for these two PARs?
- Can the multi-morbidities be comprised of multiple mental conditions (i.e., two or more psychiatric diagnoses) in addition to physical co-morbidities?
- Does the proposed intervention need to target MCC directly, or can it target more downstream consequences of MCC, such as frailty? There is substantial overlap between frailty and MCC.
- Is tobacco use/tobacco use disorder considered a chronic health condition for the purposes of these FOAs?
- Are psychosocial interventions included as areas of interest?
- My application is at the intersection of disability, cancer, and race/ethnicity and focused in women across the life course: What would be an appropriate IC?
- Is risk prediction for developing MCCs an area of interest or is it preferred to develop measurement methods to detect existing MCCs?
I do not conduct basic or mechanistic research, so is PAR-20-180 a good fit for my applied research study?

Are these funding mechanisms intended to specifically engage community and non-health sectors?

KEY OF ABBREVIATED TERMS

AIDS – Acquired Immunodeficiency Syndrome

ART – Assisted Referral Tool

COVID-19 – Coronavirus Disease 2019

CSR – Center for Scientific Review

DRR – CSR Division of Receipt and Referral

ESIs – Early Stage Investigators

FOA – Funding Opportunity Announcement

HIV – Human Immunodeficiency Virus

ICs – NIH Institutes, Centers, and Offices

MCCs – Multiple Chronic Conditions

NICHD – Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIH – National Institutes of Health

OBSSR – Office of Behavioral and Social Sciences Research

ODP – Office of Disease Prevention

ORWH – Office of Research on Women's Health

PAR – Program Announcement with special receipt, referral, and/or review considerations, as described in the PAR announcement

PDs/PIs – Program Directors/Principal Investigators