

## REQUEST FOR PROPOSALS (RFP) FOR ANCILLARY STUDIES on COVID-19 in WHI PARTICIPANTS

June 10, 2020

The Women's Health Initiative seeks concept proposals for ancillary studies designed to address COVID-19 risk factors and disease severity as well as the broader impact of the pandemic on WHI participants, such as changes in food access, stress and anxiety and other related topics. We encourage proposals that build on our well-characterized, geographically dispersed cohort coupled with the WHI COVID-19 Baseline/Core survey data (attached). Investigators new to WHI or who have not yet submitted an ancillary study proposal are particularly encouraged to submit their ideas. Also, we ask that SIG chairs work with their members to submit proposals related to their SIG topic areas of expertise.

### **Background**

The COVID-19 survey, to be administered in June-August, 2020 among all WHI participants, will assess risk factors, preventive measures, disease incidence and severity and the impact of prevention measures among our cohort of ~65,000 participants aged 72-103. These data will be collected using an online (RedCap) survey when possible and a mailed survey or telephone interview otherwise. The RedCap and telephone surveys are identical; however, the paper survey is a slightly reduced version. We hope to receive at least 50,000 responses.

***The intent of this RFP is to identify and facilitate the most promising science on COVID-19 in WHI based on the COVID-19 survey data, coupled with data collected in proposed ancillary studies that will generate new data, either by additional primary data collection or biospecimen analyses.***

### **Ancillary Study Concept Proposals**

The ASC has already reviewed and approved some COVID-19 related ancillary study proposals that were submitted as administrative supplements to existing NIH awards. We intend to build on the usual ancillary study proposal review process through the concept proposals that are received in response to this RFP. Concept proposals will provide a mechanism by which the ASC can provide a quick review of the idea proposed and will help ensure that COVID-19 related ideas are not duplicative. ASC will facilitate collaboration as needed. It is important to note that concept proposals are not required. Investigators may submit full ancillary study proposals using the standard application process described on the WHI website. However, since we anticipate a large number of COVID-related ancillary study applications, the concept review will help prevent overlap.

The ASC will begin to review concept proposals for ancillary studies in July 2020 and monthly thereafter. To be considered in any given month, please submit your concept proposal to Helen Penor at the ASC email address ([ASC@whi.org](mailto:ASC@whi.org)) by the first business day of that month.

For a concept proposal, please provide the following

1. Brief scientific premise and specific aims.
2. WHI population to be studied.
3. Primary exposure and outcome or key variable to be examined.
4. Proposing investigator(s).
5. New data to be collected/generated (include whether biospecimens will be requested).
6. Proposed funding source(s) and funding submission deadline.

### Review Process

The ASC will review concept proposals for overall scientific merit, overlap with previously approved studies, feasibility and participant burden, as appropriate. Approved concepts will be required to complete a full application and undergo the usual review process. Recognizing the many funding opportunities and associated deadlines, investigators are encouraged to discuss issues of timeline and overlap with the ASC Chair, Dr. Marian Neuhouser (mneuhaus@fredhutch.org). Expedited reviews may be granted at the chair's prerogative.