Women’s Health Initiative: Feasibility Funding Opportunities

Request for Applications

Due: January 5, 2015
Announcement of Award: February 6, 2015
Funding will come from the WHI CCC at Fred Hutch

Overview:

The WHI Extension Feasibility Study Funding Program, first released by WHI Regional Centers (RCs) in 2011, was developed to catalyze the development of ancillary study submissions by providing a mechanism to support limited acquisition of pilot data, demonstrate feasibility for the conduct of the proposed ancillary study within WHI and/or to enhance the collection of data critical for the design of a proposed ancillary study. Funds have recently been identified that can be used to support feasibility studies this year. Examples might include (but are not limited to):

- Pre-testing the feasibility of possible interventions for RCTs.
- Assessing the willingness of targeted WHI women to participate in an ancillary study.
- Developing and pre-testing a questionnaire for use in an ancillary study.
- Data analytic research proposals using Medicare data.
- Development of novel statistical methodologies using WHI data.
- Convening a group of key investigators to write a full ancillary study proposal and formalize a consortium of investigative sites.
- Assessing the use of Long Life Study biospecimen, especially RNA extracted from whole blood. (For details about the Long Life Study blood collection protocol, please refer to the blood protocol on the WHI web site.)

The feasibility funding initiative will also consider scientific proposals that will expand the core research resource. Proposals submitted under this second track should be developed by a group of investigators. Examples of topics/resources that might be responsive to this would be:

- A core analyte (or genotype) in a subset of the cohort to facilitate better definition of a phenotype (e.g. ApoE genotypes for phenotyping cognitive impairment, etc).
- Development of a set of codes and subsequent validation for specific phenotypes or health services within Medicare.
- Creating analytic resources that would be made available to multiple investigators.
- Linking to a new, outside datasource.

Detailed information on the WHI and scientific resources available to investigators can be found at: http://www.whi.org/
Review Criteria:

Priority will be given to proposals that are likely to lead to peer-reviewed funded research to be conducted within the WHI. As feasibility studies, these efforts are not expected to produce major publications themselves but rather form the foundation for high-quality, full-scale research projects. The evaluation and prioritization will consider:

- **Significance:** Does the proposal attempt to address an important health concern of aging women? Is the idea based on a conceptually sound scientific hypothesis? If successful, is the next step within the scope of WHI to address (e.g., lead to another randomized trial within WHI participants)?
- **Innovation:** Does the proposed work open a new area or significantly expand an existing area of research in WHI? Does it develop or test a new methodology or facilitate a new collaboration that may benefit WHI?
- **Approach:** Is the design sound, the measurements appropriate and the resources available to conduct this pilot research? Is it likely to produce compelling data for the next stage? Is the WHI a reasonable or necessary place to do this work?
- **Impact on WHI participants:** Is the burden on participants reasonable? Will the proposed work interfere with any ongoing WHI and previously approved ancillary study interactions with participants?
- **Investigators:** Is the expertise of the investigator team appropriate to conduct the study? Do the investigators demonstrate adequate knowledge of the current WHI resource to assure an efficient implementation and smooth integration?
- **Environment:** Are all the necessary resources identified and available?
- **Feasibility:** Can the project or portion of the project to be funded by this RFA be completed by August 31, 2015? WHI contract funds available cannot be used beyond this date.

Eligible Individuals:

At least one of the individuals competing for these funds must be associated with the WHI as an investigator or consultant on a Regional Center or Clinical Coordinating Center contract. Although scientists of any rank are eligible to compete for these funds, the review committee may give preference to early to mid-career investigators. Pre- and post-doctoral investigators may be included on a proposal but will not be considered competitive as the lead investigator.

Available Funds:

Funding for feasibility studies is anticipated to range up to $40,000 in direct costs per project (exclusive of CCC costs). The review committee may consider requests for larger amounts if particularly unique and well justified.

For proposals seeking to expand the core scientific resource, the direct costs would be limited to $80,000 and must be well justified based on scientific impact and merit.

https://www.whi.org/Documents/WHI RFA -December 2014.doc
Application and Submission Information:
See attached template

Review Process and Timeline:
➢ Proposals are due January 5, 2015
➢ Review Process:
  o Proposals will be reviewed by members of the standing Ancillary Study Committee (ASC), augmented as needed to have appropriate expertise or avoid conflicts of interest.
  o Recommendations from the ASC will go to the CCC for review of feasibility within the timeframe and budget considerations. The CCC will propose a slate of proposals to the WHI Steering Committee and NHLBI Project Office for final approval based on ASC rankings and the CCC feasibility and budget assessment. Proposals requiring participant consent will also require OSMB approval.
➢ Projected notification of award date: February 15, 2015
➢ Anticipated funding date: March 1, 2015 (this will depend on whether funding mechanism required is a subcontract or a purchase service agreement)
➢ Funding period: March 1, 2015 through August 31, 2015. All funds must be expended by August 31, 2015. No carry-over of funds can be allowed.

Submit Proposals via email to: Helen Penor (hpenor@whi.org)
WHI Feasibility Study Proposal template

Proposal Title:

Date Submitted:

Investigator(s):

Contact Information for Lead Investigator:

WHI Senior Investigator Sponsor*:

Research Plan:
Not to exceed three pages. The proposal should include:

- **Hypothesis/Statement of Study Goal**
- **Specific Aims of Proposed Study**
- **Significance**: How will the proposed study lead to the development of a more competitive ancillary study proposal; or research agenda within WHI?
- **Innovation**: Describe innovative aspects of your proposed research that will contribute to improvements, refinements, or new approaches to women’s health research.
- **Approach**: Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the study. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans, as appropriate. Describe the CCC and/or RC role in this study, if any.
- **Discussion**: Describe the anticipated next steps and how these results will facilitate them. If the goal is to develop an ancillary study proposal, include draft aims of the ancillary study.
- **Relevance to WHI**: Explain how the resources within the WHI uniquely fit the proposed study.
- **Timeline and Feasibility**: Indicate key milestones that will be met to assure completion of the project or CCC funded portion of the project by August 31, 2015.
- **References** (not included in the three-page limit)

**Budget:**
Provide a detailed budget with justification. If the amount exceeds $40K in direct costs, describe why this study merits the additional expenditure of funds. Investigator salary support is allowed but must be justified as essential to the completion of the study. All proposals will be funded by the CCC as subcontracts or purchase service agreements. Subcontracts encompass additional administrative burden so the timeline for funding and start-up may be delayed.
Allowance for this should be considered in the project timeline. Costs for any CCC work scope in support of your proposal (i.e., WHI specimen processing or mailings) do not need to be calculated prior to the submission but will be added by the CCC prior to the final review for consideration in final selection.

**Biosketch:**

Provide a biosketch (NIH format) for each proposed investigator for the study.

**Letter of Support from Senior WHI Investigator**

*A WHI Senior Investigator sponsor is not required. However, we strongly encourage you to work with a senior WHI scientist or CCC investigator as s/he will be familiar with the WHI resources/data and able to assist you in developing a competitive proposal. If you have any questions about who would qualify as a senior WHI investigator, we will assist you.*

If you have any questions, please send them to helpdesk@whi.org
WHI Feasibility Funding FAQ Addendum

1. **Q:** How do I determine if I need to include funding for the WHI CCC at FHCRC?
   
   **A:** Generally, if a study will access specimens from the WHI repository, or consent participant at more than one WHI Regional Center, then the CCC will need to be involved. However, these costs will not be included in the $40,000 limit. The CCC will contact you after your proposal is submitted.

2. **Q:** When should I contact the CCC about a scope of work and budget?
   
   **A:** The CCC costs for a scope of work will be determined after ASC review.

3. **Q:** Do we need institutionally signed documents and letter of intent for the Feasibility Study submission?
   
   **A:** Applicants do not need a letter of intent and institutionally signed documents until after review/approval.

4. **Q:** If funded, from what institution will we be receiving our award and what type of funding mechanism will it be?
   
   **A:** Funds will be provided by the Women’s Health Initiative Clinical Coordinating Center at Fred Hutch. The funding mechanism will depend upon such factors as the type of work to be performed, whether the CCC is funding the PI’s scientific involvement, or whether the work can be defined as a fixed cost or cost-reimbursable. If your project requires the CCC to issue a subcontract, please be aware that this may take a minimum of 1.5 months to set into place, although the subcontract could retroactively start on March 1, 2015. If you would like more information about whether your proposal would likely initiate a Purchase Order or a Subcontract, please contact helpdesk@whi.org.

5. **Q:** Do we need to seek IRB approval, or is the WHI CCC the IRB of record?
   
   **A:** If approved and chosen for funding, you will need to receive local IRB approval for your study. The WHI CCC is not IRB of record for studies ancillary to the WHI protocol.

6. **Q:** My lab requires that the samples we provide have been plated. Will the sample processing lab plate samples?
   
   **A:** The sample selection and processing for the funded feasibility studies necessarily must be as simple as possible. As sample plating requires additional CCC and processing lab staff effort, plating of samples is only possible for studies with less than 500 samples (~5 plates).

7. **Q:** My lab requires special batching or sorting of samples. Will these special lab requirements be provided by the sample processing lab?
A: The sample selection and processing for the funded feasibility studies necessarily must be as simple as possible. As special batching and/or sorting requires additional CCC staff effort, this service will not be provided for the feasibility studies. However, it is possible that the CCC could provide the data to you that would allow you to inform the lab of the desired sample ordering.

8. **Q:** Is it possible to send an aliquot of sample from each participant to several labs?

A: The sample processing for the funded feasibility studies necessarily must be as simple as possible. Rather than having our sample processing lab create multiple aliquots from each sample, one of your labs will need to take care of this task.

9. **Q:** It is essential that I test sample from exactly X case/control pairs. What if there is not sufficient sample of one of the cases in one of my case/control pairs?

A: The participant selection for a study uses the best possible information on sample availability. However, the repository database is not perfect. So, sometimes sample is not available for a selected participant. Rather than having an exact number complete case/control pairs, we suggest you simply increase your sample size by ~ 3% to make sure that you have enough complete case/control pairs.

10. **Q:** The first phase of my study is a ‘discovery’ step that involves pooling of sample from several cases or controls. Will the sample processing lab do the pooling and ship the resulting sample pools to my lab?

A: The sample processing lab will not be able to prepare pools of samples for feasibility studies. However, we can provide your lab with the information it would need to prepare its own pools.

11. **Q:** Are there any limits as to how much sample I can request?

A: Without significant scientific justification, sample volumes are limited to the following amounts:

- Serum, Plasma, RBCs: 250 µl
- Urine: 500 µl
- DNA: 2 µg
- RNA: 0.5 µg

Please note that these sample volumes include any necessary ‘dead volume’ that might be required for an assay. If your test requires exactly 200 µl, it would be appropriate to request 250 µl because one can never get out of a vial exactly the amount that was put into the vial.