Women's Health Research at Yale

▶ Better science, better lives ▶ ▶

Pilot Project Program: Full Application Instructions

(BY INVITATION ONLY)

All applications must be assembled in the order listed below and adhere to the following requirements:

- Use only 11-point Arial-type font on single-sided, single-spaced sheets
- Place the Principal Investigator's name (Last, First and Middle Initial) as a header on each page (except the Face Page)
- Number all pages consecutively
- Leave a half-inch margin on all sides
- Abide by page limitations noted below

For a copy of these instructions and the full application form, visit our website: <u>https://medicine.yale.edu/whr/science/pilot-funding/</u>

Questions? Contact the WHRY Office at <u>marco.mutonji@yale.edu</u> early in the grant cycle.

Full application components:

1. Face page

Use the Women's Health Research at Yale Face Page Form (pages 1-2) and complete all information. Scanned Signatures are acceptable for digital submissions.

2. Table of contents

Use form provided (page 3).

3. Abstract, work location, and personnel

Use form provided (page 4). Provide an abstract describing the project, and:

- List work location(s).
- List all Key Personnel (include Principal Investigator, Co-Investigators, and Other Significant Contributors) with organization and departmental affiliation(s), percent and calendar month effort(s), and respective role(s) on the proposed project for each Key Personnel.
- Provide areas of expertise required by reviewers.
- Use an additional sheet if necessary and label 4a.

4. Budget

Use NIH budget form (pages 5 & 6) provided.

- Provide percent effort as well as calendar month effort for all personnel. Use NIH Salary Cap and University Funds Fringe Benefits.
- Provide specific costs for each line item. For a two-year grant, an inflation rate of 3% is acceptable

> The budget cannot exceed \$35,000 for a Pilot Project Award application, or \$50,000 for a Pioneer Award application in total direct costs whether the budget period is one-year or two-years.

Please note indirect costs will not be provided. Budget not to exceed two (2) pages.

5. Budget justification

Use the provided Continuation Page.

- Provide a written justification for all personnel, their percent effort, and their specific role on the project (include Other Significant Contributors not requesting salary compensation).
- Provide dollar amounts and a brief, clearly written justification for all items for which funding is requested.
- Expenses for travel to professional meetings and publication costs are not allowed. The Program discourages the use of monies from this grant to purchase high-cost equipment or computers, and individuals with K awards are ineligible to include salary/fringe support in this application.
- Include a statement disclosing any support that you have pending and a statement regarding costsharing if reduced costs can be demonstrated by using existing resources to offset the expenses of the project.
- LIST DIRECT COSTS ONLY.

Budget Justification not to exceed two (2) pages.

6. Practical benefit for women'shealth

Use the provided Continuation Page.

- Clearly state the issue in women's health that motivates this proposal: What is the problem you hope to address?
- Identify the population(s) who would benefit from this project and the specific benefits.
- Clearly state the logical connection between the hypothesis under investigation and the ultimate benefit you hope to generate.
- In the clearest language possible, describe how this research will help women.
- Include a time frame to realize the stated benefits.

Continuation Page not to exceed one (1) page.

7. Research plan

Use the provided Continuation Page. Include each of the following sub-headings in the order below and **BOLD** those in the text.

I. SPECIFIC AIMS

State the specific aims of the proposal. Include time frame to achieve the stated research goals.

II. BACKGROUND AND SIGNIFICANCE

Provide experimental rationale and significance of your research goals, including theoretical and empirical context.

III. PRELIMINARY DATA

Present preliminary data supporting project goals.

IV. DESIGN AND METHODS

Clearly state hypotheses, a well-devised methodology, a description of techniques or behavioral assays including assessments of reliability and/or accuracy, a clear data analytic plan for testing hypotheses, a justification of sample size, and a careful consideration of possible problems and/or confounding variables.

V. EXTERNAL FUNDING

Include one paragraph on how this research may lead to additional funding.

Sex and gender:

(a) Ensure that proposed human study participants are described in terms of sex or gender, depending on the focus of your study, <u>using the definitions recommended by the NIH</u>:

"Sex" refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. "Gender" refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time. All individuals act in many ways that fulfill the gender expectations of their society. With continuous interaction between sex and gender, health is determined by both biology and the expression of gender.

(b) Ensure that vertebrate animals being studied in laboratory research are characterized as females or males.

Race and ethnicity:

Ensure that proposed human study participants are described in terms of race and ethnicity consistent with the <u>2021 JAMA Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals.</u>

The Methods section should include an explanation of how participant sex, gender, race, or ethnicity are defined and the source of the classifications used (e.g., self-report or selection, investigator observed, database, electronic health record).

Despite limited sample sizes, every attempt should be made to examine trends in the data relative to sex and gender, and race and ethnicity.

The Research plan is not to exceed six (6) pages. Illustrations, photographs and/or graphs are included within these page limitations.

8. Literature cited

List first three authors followed by *et al.*, complete title, journal, volume, page(s), and year. *Not to exceed two* (2) pages.

9. Biographical sketch and other support

Use the NIH Biosketch format (<u>https://grants.nih.gov/grants/forms/biosketch.htm</u>), also submit the NIH updated format for Other support (<u>https://grants.nih.gov/grants/forms/othersupport.htm</u>).

Biosketches must include a Personal Statement that describes the person's experience and interest as it

Other considerations

10. Letters from consultants/collaborators

Include letters of support from all Other Significant Contributors (e.g., consultants/collaborators) describing their support and relationship to the project.

11. Appendices

No appendices, publications, or additional attachments will be accepted.

12. Human subjects

No application involving human subjects, tissues, or cell lines will be accepted for funding without a Yale Internal Review Board number, Yale-affiliated hospital's IRB number, or letter of exemption. For information regarding guidelines, contact the appropriate office.

13. Animal subjects

No research involving animals will be accepted for funding without an Institutional Animal Care and Use Committee (IACUC) number. No animal research conducted at a Yale-affiliated hospital will be funded without the appropriate affiliated Institutional Review Board approval. No animal research conducted at any location will be funded without IACUC approval.

Application approval prior to submission

Prior to submission, review is not required by Yale's Office of Sponsored Projects. It is required by the appropriate department business office manager and chair for budget approval and signature(s).

Application review process

Full applications received by the center's office are peer-reviewed. The center, with the assistance of its Scientific Review Committee, will conduct the final review. **The Center does not provide critiques for unfunded proposals. Announcements of grant award(s) are anticipated in June 2024.**

Submission

Complete applications must be received by Friday, January 5, 2024, at 12:00 PM (noon). **NO EXTENSIONS WILL BE GRANTED.** Applications that do not meet the above guidelines will be returned to the applicant without review.

Applicants must submit: An electronic copy in Word or PDF format of the entire grant application (Including Letters of Support) to <u>marco.mutonji@yale.edu</u>