Funding Opportunity for Pilot and Feasibility Studies: The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium

I. Funding Announcement

The Scientific and Data Coordinating Center (SDCC) for the Prevention of Lower Urinary Tract Symptoms (PLUS) in Women Research Consortium, supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), invites research grant applications to conduct pilot and feasibility studies that support the mission of the PLUS Consortium, which is to identify promising strategies for promoting bladder health and reducing lower urinary tract symptoms and conditions in women throughout the lifespan. Amount and number of awards will be dependent upon funds available (see below).

II. Overview of the PLUS Research Consortium

Background

Lower urinary tract symptoms (LUTS) are common in women, resulting in significant but under-recognized quality of life, public health, and financial burdens. Stigma around LUTS and the belief among many women that they are inevitable frequently results in symptoms going unreported and therefore untreated. Thus, many women adopt unhealthy coping behaviors, such as limiting physical activity, social isolation or restricting fluid intake. The features of a “normal bladder,” healthy bladder function or the behaviors that may promote bladder health over a lifetime, have yet to be identified. Additionally, efforts to delineate causes of LUTS have focused primarily on biologic factors, without sufficient consideration of the impact of behavioral and psychological/executive function, or sociocultural contributors. In response, PLUS has adopted use of the social ecological model (SEM) which considers interactions between social context and biology across the lifespan and views health behaviors as being determined by intrapersonal factors, interpersonal processes and primary groups, institutional factors, community factors, and public policy.

Framing the PLUS consortium goals broadly (bladder health) provides for the possibility that PLUS Consortium findings will impact our understanding and ultimately clinical management of numerous urologic conditions. The Consortium will obtain information from adolescents and women of various ages through multiple, complementary research approaches, including qualitative and quantitative research, to characterize the healthy bladder and identify personal behavior and other factors associated with normal bladder function. They will also seek to identify protective factors for long-term bladder health and risk factors for developing lower urinary tract conditions. The ultimate goal is to obtain the necessary information to plan future studies, including interventions, to promote bladder health and prevent LUTS in women throughout their lives.

The evidence gaps in defining a pathway to bladder health and LUTS prevention are extensive, requiring the PLUS Consortium to prioritize which questions to address. This solicitation provides an opportunity for additional, non-PLUS investigators to contribute to this growing evidence base through participation in a new PLUS Pilot and Feasibility (or small grant) Program.
II. PLUS Research Consortium Pilot and Feasibility Studies

The purpose of this announcement is to solicit grant applications for pilot and feasibility studies to increase our understanding of risk and protective factors important for promoting bladder health and preventing LUTS in women across the entire lifespan. Applicants are encouraged to propose studies that will add value to the PLUS Consortium’s goal to understand the spectrum of bladder health and risk and protective factors among women and girls in the general population. These include biological, social, and psychological factors that can be explored as influencing bladder health across the lifespan.

Applications must describe how proposed studies address the PLUS Consortium goals of informing future LUTS prevention intervention studies. Basic science, clinical (qualitative and quantitative) and epidemiologic studies that can be accomplished within the allowed budget are considered in scope for this funding opportunity.

Studies proposing the use of innovative methods and technical approaches are encouraged, though not required. Studies that propose using available resources developed by clinical science or epidemiologic studies to address questions relevant to the goals of the PLUS Consortium are also encouraged. Appropriate letters of collaborative support on and/or authorization for sharing study data or sample repositories must be obtained from the relevant study groups and included in the grant application.

Applicants must provide milestones that should be achieved over the term of the award. It is anticipated that hypothesis testing or hypothesis generating studies supported through this effort may provide a foundation for future research applications (e.g., R01s, R21s, etc.).

Interested applicants are strongly encouraged to contact the NIDDK Project Scientist (see Section VIII) early in the application process to avoid submission of a proposal that overlaps with PLUS ongoing or planned studies.

Approaches and areas of interest include, but are not limited to:

- Use of existing cohorts or databases to identify new or validate risk factors for LUTS conditions across the lifespan (adolescence to noninstitutionalized older women)
- Innovative approaches to examine clinical and biological data that provide an underlying understanding of bladder health
- Assessment of novel underlying mechanisms by which women retain a healthy bladder or begin to transition toward conditions involving LUTS
- Basic science studies to examine potential cellular/molecular contributors to retaining healthy bladder function
- Pilot studies for testing potential interventions for promoting bladder health
- Recruitment of study participants at the applicant institution to perform in-depth characterization (phenotyping) of women with varying degrees of bladder health
- Mining existing biosamples (e.g. proteomics, metabolomics, microbiomics) that are linked with clinical data for discovery or validation of markers for bladder health or a LUTS condition

The following topics are considered non-responsive to this solicitation:
PREVENTION OF LOWER URINARY TRACT SYMPTOMS IN WOMEN

A Research Consortium of the National Institutes of Health

- Studies that are duplicative or propose significant overlap with past or ongoing/planned PLUS Consortium studies
- Development or study of a rodent model system as the primary aim/goal

The application must identify a Principal Investigator (PI) (or multiple PIs). Additional personnel should be included that permit formation of a team of investigators with sufficient and complementary expertise. Transdisciplinary approaches are encouraged. Clinical expertise relevant to the care and treatment of LUTS patients should be included to ensure a strong focus on clinically significant questions and potential to complement PLUS Consortium goals. Studies may involve investigators from more than one institution, if well justified.

Investigators may choose to utilize resources at the PLUS Consortium SDCC where expertise on study design, data collection, management and analysis resides. Those interested in such support would need to include costs in the proposal budget and should contact Keith Vargo, PLUS Scientific and Data Coordinating Center (SDCC) Research Operations Manager at vargo001@umn.edu.

IV. Available Funds and Additional Considerations

In 2017, NIDDK plans to allocate up to $500,000 through single, one-time awards of up to a maximum requested budget of $100,000 Total Costs (including direct and associated indirect costs).

Funded investigators will be responsible for using funds at a rate which allows for sufficient time to completely address the proposed Specific Aims and Goals. Studies should include a proposed plan for utilization of resources over a suitable period. Final awards will be issued through sub-contracts with the PLUS Consortium SDCC at the University of Minnesota.

Funded investigators will make 2 presentations to the PLUS Steering Committee via webinar:
- Research plan after receipt of award
- Study findings after completion of the study

V. Eligibility

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Foreign institutions are eligible for this announcement. Current PLUS Consortium grantee institutions are eligible to submit grant applications, but Principal Investigators (PIs) named on applications in response to this opportunity must have their primary appointment in a Department/Division that is different than the primary affiliation of the current PLUS PI or co-PI. Current PLUS Consortium investigators are not eligible to apply as Principal Investigators. However, current PLUS Consortium PIs and key investigators may be named as non-paid consultants.
VI. Application Format

Applications submitted in response to this announcement will generally follow the guidelines for NIH R01 applications which use standard SF424 forms. All page limitations are described in the SF424 Application Guide and the NIH Table of Page Limits (http://www.grants.nih.gov/grants/forms_page_limits.htm) must be followed with the following exception: The Research Strategy section of the application may not exceed 6 pages.

Applications will be submitted electronically at: https://proposalcentral.altum.com/ (see instructions in Section VII).

For information on the SF424 application format see: http://grants.nih.gov/grants/funding/424/index.htm.

Counter signatures from Institutional Grants Offices are required at the time of submission.

Applicants are encouraged to consider the review criteria described below in the development of their proposals (see Section VIII).

VII. Key Dates and Application Submission

Key Dates
Release date: February 16, 2017
Application Receipt date: June 19, 2017
Review: July 27, 2017
Sub-contract Award: September, 2017

How to Send Applications
Applications will be completed online through proposalCentral. The proposal format and review process generally follows NIH RO1 protocols.

1. Go to https://proposalcentral.altum.com/ to register for an account.
2. Validate your account by entering a confirmation number that will be emailed to you by proposalCENTRAL.
3. Fill out your “Professional Profile” and link your account to your respective institution or organization.
4. Click on the gray “Grant Opportunities” tab listed in the upper right hand corner of the screen.
5. In upper left hand corner click on blue “Filter by GrantMaker” drop-down and choose “University of Minnesota/NIH Pilot Studies”.
6. Click on “Apply Now” button next to the application name.
7. Enter in your “Project Title” and then click on “Save”. You will be now able to see all of the required sections. Follow the instructions on each page.
8. Once you have completed your application, click on the “Validate” link to make sure you have included all required information.
9. Click on the “Submit” link.
Contact the PLUS SDCC Research Operations Manager for technical questions about application submission (see Section IX for contact information) or refer to section VI above. Applications must be received on or before the above receipt date. Late, non-responsive, or incomplete applications will not be considered.

**Do not submit applications electronically through Grants.gov.**

**VIII. Application Review**

**Review Process and Criteria**
The PLUS Consortium External Experts Panel (EEP) will conduct the application review. Additional ad hoc reviewers may be added, as needed, to ensure adequate expertise. The application review group will be led by a member of the EEP and coordinated by the NIDDK Project Scientist.

The EEP will initially assess the points below and may consult with the PLUS Consortium Executive Committee on a case-by-case basis.

- Relevance of the proposed study to the goals of the PLUS Consortium
- Potential overlap with completed or planned PLUS Consortium initiatives
- Appropriateness of funds to support collaborative PLUS Consortium activities

For applications that meet the criteria above, reviewers will be asked to judge the overall scientific merit of the application and the likelihood of the proposal for success including the practicality of completing the research with the resources requested.

Review criteria will include:

- Merit and feasibility of research study design and methods
- Qualification and experience of the Principal Investigator and assembled team
- Appropriateness of proposed timeline and budget, including support from the PLUS Consortium SDCC, if needed

No numerical scores will be assigned; however, a brief critique will be provided to applicants. The NIDDK will use EEP comments in award selection.

**Funding Decisions**

Funding decisions will be made by the NIDDK and will be based on (1) an assessment of scientific merit and other review criteria and recommendations from the PLUS Consortium EEP and ad hoc reviewers, and (2) availability of funds. All awards are subject to possible EEP-recommended and/or administrative reductions in requested funds. The NIDDK retains all rights and responsibilities outlined in the original PLUS Consortium Funding Opportunity Announcement (RFA-DK-14-004 and RFA-DK-14-018).

For those applications selected to receive awards, the final level of funding and sub-contract terms will be determined by NIDDK following discussions between the Principal Investigator (and respective institutional Grants Office) and the PLUS Consortium SDCC.
Resubmissions and Appeals
This is a one-time Funding Announcement. Revised applications will not be accepted. No Appeals to the Scientific Review will be considered.

IX. Additional Information and Questions

The following will provide additional background on the PLUS Consortium:

PLUS Consortium website: http://www.plusconsortium.edu
Link to PLUS Consortium Funding Initiatives (RFAs):

Additional details and information regarding PLUS Consortium studies and resources are available upon request. Direct questions to either the NIDDK Project Scientist and/or the PLUS Consortium SDCC Research Operations Manager:

Tamara G. Bavendam MD, MS
PLUS Research Consortium Project Scientist
Director, Women’s Urologic Health
Division of Kidney, Urologic and Hematologic Diseases
NIDDK, National Institutes of Health
2 Democracy Plaza, Room 6081
6707 Democracy Blvd.
Bethesda, MD 20892-5458
Phone: 301-594-4733
FAX: 301-480-3510
E-mail: tamara.bavendam@nih.gov

Keith Vargo
Research Operations Manager
PLUS Scientific and Data Coordinating Center (SDCC)
University of Minnesota
School of Public Health - Division of Biostatistics
2221 University Ave SE, Suite 200
Minneapolis MN 55414 USA
Phone: 612-626-9017
Fax: 612-625-0080
E-mail: vargo001@umn.edu