



PREVENTION OF LOWER URINARY TRACT SYMPTOMS

A Research Consortium of the National Institutes of Health

Funding Opportunity for Pilot and Feasibility Studies: Social-Ecological Risk Factors for Lower Urinary Tract Symptoms and Protective Factors for Long-term Bladder Health

I. Funding Announcement

The Scientific and Data Coordinating Center (SDCC) for the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium, supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Office of Research on Women's Health (ORWH) at the 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, and/or expand PLUS work to identify and understand sex and gender differences in social-ecologic factors for bladder health and conditions associated lower urinary tract symptoms. It is expected that three awards with total costs of up to \$150,000 each will be awarded.

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 these conditions are inevitable frequently results in symptoms going unreported and therefore untreated. Thus, many women adopt unhealthy coping behaviors, such as limiting physical activity, restricting fluid intake, or social isolation. 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 behavior, mind and mental functioning, cultural contributors, or social determinants of health. 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 as bladder health provides for the possibility that PLUS Consortium findings will affect 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 both protective factors for long-term bladder health and risk factors for developing lower urinary tract conditions. The long-term goal is to obtain the necessary information to plan future studies, including interventions, to promote bladder health, and to prevent LUTS in women throughout their lives as well as support institutional and societal policy changes.



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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.

III. Purpose of the Pilot and Feasibility Studies

This announcement is to solicit grant applications for pilot and feasibility studies to address environmental and contextual factors in support of the overall work of the PLUS Consortium and/or to explore sex and gender differences in environmental and contextual factors relating to bladder health. It is distinct from a previous successful RFA from 2017, which was to increase our understanding of risk and protective factors important for promoting bladder health and preventing LUTS in women across the entire lifespan. Proposals in that initial program included studies to examine biological, social, and psychological factors that influence bladder health across the lifespan, but not at an environmental level.

The studies for this RFA should focus on environmental and contextual risk factors of lower urinary tract symptoms. Specifically, the environmental and contextual risk factors studied should reflect the social-ecological domains of the conceptual framework that guides PLUS research previously published by Brady et al (DOI: 10.1002/nau.23787). Those social-ecological areas of environmental interest identified in the PLUS conceptual model are:

- Societal/Community - Factors that broadly influence the health of populations and communities
- Institutional - Characteristics that vary across workplaces, schools, clinics, and other institutions
- Interpersonal - Characteristics that vary across families, friendships, and other close relationships

Applications must describe how proposed studies could address PLUS Consortium goals of informing future LUTS prevention intervention studies and/or supporting policy changes. Qualitative, 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 ongoing or planned PLUS studies.

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



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- Qualitative or quantitative or mixed research on persons or institutions who make and enforce rules, policies, regulations about access to toilets (teachers, principals, superintendents, employers, business owners with restrooms available for patrons versus the public, prison supervisor).
- Qualitative or quantitative or mixed research with those who make decisions or recommendations about toilet location, size, number, and design (e.g., designated for male, female, "all gender," families, individuals with disabilities) in places of employment or public spaces.
- Qualitative or quantitative or mixed research with families, friendship networks, and networks within institutions (e.g., schools, workplaces) to understand practices and norms that may influence the development and maintenance of behavioral habits related to toileting (e.g., fluid intake or restriction; voiding with and without urge, or ignoring urge; toileting position, particularly in public spaces).
- Use of existing cohorts or databases to identify new or validate suspected economic or environmental and/or contextual risk factors for LUTS conditions across the lifespan (adolescence to noninstitutionalized older adults).
- Pilot studies for developing and evaluating the feasibility and acceptability of potential interventions on environmental or contextual factors for promoting bladder health.
- Assessment of potential impacts on bladder health resulting from the location, design, structure, cleanliness, safety of, provision of resources (e.g., disposable toilet seat covers) within existing toileting facilities, etc.
- Qualitative research exploring sex and gender differences in environmental and contextual factors influencing bladder health and lower urinary tract symptoms. Factors may include toileting infrastructure and access, perceived toileting norms, time restrictions, family and peer influences, etc.

The following are considered non-responsive to this solicitation:

- Studies that are duplicative or propose significant overlap with past, ongoing, or planned PLUS Consortium studies.
- Studies including exclusively men and/or adolescent boys.
- Studies focused on individual biological factors that may impact bladder health.
- Studies proposing use of animals.

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. PIs need not have expertise in bladder health and LUTS, provided that another team member has this expertise. Transdisciplinary approaches are encouraged. Studies may involve investigators from more than one institution, if well justified and feasibility is demonstrated.

Investigators may choose to utilize resources at the PLUS Consortium Scientific and Data Coordinating Center (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 SDCC Research Operations Manager at vargo001@umn.edu.

IV. Available Funds and Additional Considerations



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\$450,000 through single, one-time awards of up to a maximum requested budget of \$150,000 Total Costs (including direct and associated indirect costs).

Funded investigators will be responsible for using funds at a rate that allows 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 two 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 from 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.



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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: December 18, 2018

Application Receipt date: April 1, 2019

Review: May 15, 2019

Sub-contract Award Start Date: July 1, 2019

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.



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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:

- Alignment with PLUS goals
- 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).



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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):

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-14-004.html>

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-14-018.html>

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:

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Working PLUS Conceptual Framework

Adapted from Thomas Glass and Matthew McAtee (Social Science & Medicine, 2006)

Categorizing risk and protective factors for bladder health / LUTS

