NOTICE OF OPPORTUNITY FOR CLINICAL TRIAL COLLABORATION

UTILIZATION OF MID-URETHRAL SLINGS, RETROPUBIC AND TRANSOBDURATOR SLING PLACEMENT DEVICES IN A NIH SPONSORED MULTI-CENTER CLINICAL TRIAL IN WOMEN WITH STRESS URINARY INCONTINENCE.

The National Institute of Diabetes and Digestive and Kidney Disease of the National Institutes of Health (NIH) of the Department of Health and Human Services (DHHS) seeks collaboration with industry to provide mid-urethral slings and retropubic transobdurator sling placement devices in a NIH-sponsored multi-center clinical trial in women with stress urinary incontinence.

INTRODUCTION: The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) is planning to conduct a randomized controlled clinical trial to evaluate and compare approaches (retropubic and transobturator) for surgical treatments of stress urinary incontinence in women. The trial will be conducted by investigators participating in the Urinary Incontinence Treatment Network (UITN). The two-arm trial will enroll approximately 500 women and have equal randomization to two surgical approaches, either a retropubic mid-urethral sling placement approach or a transobturator mid-urethral sling placement approach. Enrollment is expected to be completed over 2 years with follow up of a minimum of 24 months and as long as 48 months. Enrollment will occur at nine participating clinical centers (William Beaumont Hospital, Royal Oak, Michigan; Loyola University, Chicago, Illinois; University of Alabama at Birmingham, Birmingham, Alabama; University of California at San Diego; University of Maryland, Baltimore, Maryland; University of Pittsburgh, Pittsburgh, Pennsylvania, University of Texas at Dallas; University of Texas at San Antonio, and the University of Utah, Salt Lake City, Utah). It is possible 1-3 additional centers will be added. Central data collection and analysis will occur at the NIDDK funded Data Coordinating Center at the New England Research Institutes, Watertown, Massachusetts.

STUDY GOALS: The primary aim of this randomized clinical trial is to compare objective cure rates for stress incontinence as well as complication rates at 1 and 2 years between these two surgical approaches. Another primary goal is to compare bother scores from stress urinary incontinence between these two surgical approaches at 1 and 2 years.

Other study aims include:

- Comparison of the morbidity between the two approaches which will include intraoperative injury, voiding dysfunction, changes of anatomic urethral support, sling erosion, and other complications.
- Comparison of patient satisfaction and quality of life variables between the two different approaches.
- Comparison of the subjective cure rates of stress incontinence and overall incontinence between the two approaches.

SUPPLEMENTAL INFORMATION: In 2000, the NIDDK established the Urinary Incontinence Treatment Network (UITN). The purpose of the UITN is to conduct high quality randomized controlled clinical trials of urinary incontinence. Currently, the UITN is completing a trial comparing two surgical procedures for women with stress urinary incontinence, "A Randomized Clinical Trial of the Burch Modified Tanagho and Autologous Fascia Sling Procedures." The second protocol, developed by the UITN investigators is: "Retropubic Mid-urethral Sling (RMUS) vs. Transobturator Mid-Urethral Sling (TOMUS)". Although this protocol has been recently approved by an independent NIDDK-appointed Data and Safety Monitoring Board and patient recruitment is anticipated to begin in late winter to spring 2006, the collaborator(s) will, nonetheless, have the opportunity to comment on the study protocol. The Collaborator(s) will also participate as an ex-officio member of the Steering Committee. It is anticipated that the duration of this trial will be at least 4 years, a 2 year recruitment followed by a minimum of 24 months follow-up. The collaborator(s) will need to provide products (slings) and devices for placement (disposable per patient use kits or non-disposable, sterilizable instruments) at the time of the surgical procedures. It is anticipated that the need of the products will be during the surgical phase of this study, during the initial 24 month recruitment phase and surgical placement of sling of this trial. The Collaborator (s) is (are) expected to provide the products (mid-urethral slings) and/or the placement device product line (either disposable per use kits or non-disposable, sterilizable instruments) for free without charge. The Collaborators may provide either or both sling products and/or placement device products or instruments. The Collaborator(s) may have access to information about the outcome of the study at the same time as the participating investigators. If desired, the Collaborator(s) may participate as a member of the publication committee. A Clinical Trials Agreement between the NIDDK and the Collaborator(s) will need to be executed prior to shipment of the products or placement kits or surgical instruments.

CAPABILITY STATEMENTS: A Selection Committee will utilize the information provided in the "Collaborator Capability Statements" to help in their deliberations. It is the intention of the NIDDK that qualified applicants will have the opportunity to provide information to the Selection Committee through their Capability Statements. The Capability Statement may not exceed 10 pages and should address the following criteria: time line for ability to ship sling product or retropubic or transobturator device kits or instruments after selection of Collaborator is determined and prior studies and approval of safety and use of their product.

TERMS: The Collaborator will be expected to execute a Clinical Trial Agreement, an example of which can be found at http://techdev.niddk.nih.gov/CTA-device-extramural.doc. No funding from the government is available.

SUBMISSION DATES: A written statement of interest must be submitted by 22 August 2005 and all Collaborator Capability Statements must be submitted by 6 September 2005.

CONTACT INFORMATION: Submit statements of interest and Capability Statements to:

Rochelle S. Blaustein, J.D.
Office of Technology Transfer and Development
National Institute of Diabetes and Digestive and Kidney Diseases
12 South Drive, Room 3011, MSC 5632
Bethesda, MD 20892-5632.

For Scientific Inquiries contact:

Debuene Chang M.D.
Director, Urology
Women's Urological Health
Division of Kidney, Urologic & Hematological Diseases (DKUHD)/NIDDK
6707 Democracy Blvd., Room 613, MSC 5458
Bethesda, MD 20892-5458
Telephone: 301-594-7717
Fax: 301-480-3510
E mail: Changtd@niddk.nih.gov
or
John W. Kusek, Ph.D.
Director, Clinical Trials
Division of Kidney, Urologic & Hematological Diseases (DKUHD)/NIDDK
6707 Democracy Blvd., Room 617, MSC 5458
Bethesda, MD 20892-5458
Telephone: 301.594.7735
Fax: 301.480.3510
E mail: KusekJ@extra.niddk.nih.gov
or
Leroy M. Nyberg, Jr., Ph.D., M.D
Director, Urology Programs, DKUHD/NIDDK
6707 Democracy Blvd., Room 627, MSC 5458
Bethesda, MD 20892-5458
Telephone: 301.594.7717
Fax: 301.480.3510
E mail: NybergL@extra.niddk.nih.gov

A formatted version of the Notice of Opportunity will be posted at:
http://TechDev.Niddk.nikh.gov/UITN.SUI.PDF.