NOTICE OF OPPORTUNITY FOR CLINICAL TRIAL COLLABORATION

UTILIZATION OF AN ANTIMUSCARINIC ANTICHOLINERGIC DRUG IN A NIH SPONSORED MULTI-CENTER CLINICAL TRIAL OF COMBINED BEHAVIORAL THERAPY AND DRUG THERAPY IN WOMEN WITH URGE URINARY INCONTINENCE

The National Institute of Diabetes and Digestive and Kidney Diseases seeks of the National Institutes of Health (NIH) of the Public Health Service of the Department of Health and Human Services seeks collaborations with Industry to provide an antimuscarinic/anticholinergic drug for use in a National Institutes of Health sponsored multi-center clinical trial comparing drug therapy combined with behavioral therapy versus drug therapy alone on the frequency of episodes of urge urinary incontinence in women.

INTRODUCTION: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is planning to conduct a randomized controlled clinical trial to evaluate if the addition of behavioral treatment to drug therapy for the treatment of women with urge urinary incontinence will substantially increase the number of patients who are able to discontinue drug therapy and sustain a significant reduction of incontinence. The two-arm trial will enroll approximately 270 women over a 12-month period and randomize them to either drug therapy alone or a combination of behavior therapy and drug therapy. The drug will be administered in an unmasked fashion. 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). 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 test if the addition of behavioral treatment to drug therapy for the treatment of urge incontinence in women will increase the number of patients who can discontinue drug therapy and sustain a significant reduction of urinary incontinence (i.e., 70% fewer incontinence episodes compared to baseline) compared to drug therapy alone.

Other study aims include:

1.) to test whether the effectiveness of drug therapy can be enhanced by combining it with components of behavioral intervention;
2.) to determine the cost-effectiveness of combining behavioral and drug therapy in clinical practice; and
3.) to examine the long-term durability of drug and behavioral treatments.

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 conducting a trial comparing two surgical procedures for women with stress urinary incontinence. A second protocol has now been developed by the UITN investigators entitled, “The Effects of Adding Behavioral Treatment to Drug Therapy: Treatment Outcomes and Response to Drug Withdrawal”. This protocol has been recently approved by an independent NIDDK appointed Data and Safety Monitoring Board . It is anticipated that patient recruitment will begin in the spring 2004. However, the Collaborator will have the opportunity to comment on the study protocol. The Collaborator will also participate as an ex-officio member of the Steering Committee. The duration of the trial will be approximately 20 months; a 12-month recruitment period and a minimum of 8 months follow-up. The Collaborator providing the antimuscarinic/anticholinergic drug will be expected to provide free drug for the 8-week drug

treatment period for approximately 270 study participants. The Collaborator may have access to information about the outcome of the study at the same time as the participating investigators. The Collaborator may participate as a member of the publication committee. A Clinical Trials Agreement between the NIDDK and the Collaborator will need to be executed prior to drug shipment.

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 provide drug after selection of Collaborator is determined, approved daily dose of drug, previous studies of efficacy of drug in treating women with overactive bladder/urge incontinence, and known side-effects of drug.

SUBMISSION DATES: A *written statement of interest* must be submitted by **1 August 2003** and all *Collaborator Capability Statements* must be submitted by **15 August 2003.**

CONTACT INFORMATION: Submit statements of interest and Capability Statements by E mail, facsimile or other mail delivered by the submission date to:

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