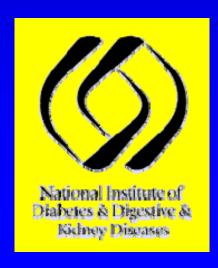
A Multidisciplinary Approach to the Study of Chronic Pelvic Pain Syndromes: The MAPP Research Network

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GOALS

- Rationale for Development of the MAPP Research Network
- MAPP Research Network Goals, Features, and Scientific Priorities
- Organization of the MAPP Research Network
- Highlighted MAPP RFA/Network Q/A

Chronic Pelvic Pain Syndromes: NIDDK Research Efforts

Urologic Chronic Pelvic Pain Syndromes

- ✓ Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS)
- ✓ Chronic Prostatitis/Chronic Pelvic Pain (CP/CPPS)

NIDDK Research History

- ✓ Multiple clinical and basic science projects
 - No statistically significant effective treatment options identified
 - No significant insights into etiology or pathophysiology

Positive Findings

- ✓ Many current therapies ineffective in randomized trials
- ✓ Urologic chronic pain syndromes have associated co-morbidities which are under studied, suggesting these are systemic disorders requiring a multidisciplinary approach

NIDDK Initiative: <u>Multidisciplinary Approach</u> to the Study of Chronic <u>Pelvic Pain</u> (MAPP) Research Network

Primary Objectives:

- ✓ Utilize a multidisciplinary and highly collaborative combined basic and clinical approach to study urologic chronic pain as a systemic disorder (e.g associations between urologic and non-urologic pain conditions: CFS, fibromyalgia, IBS, migraine headache, and vulvodynia)
- ✓ Understand the underlying disease pathophysiology and risk factors using select cohorts and human study material (e.g, tissue, serum, urine, radiological studies, etc)
- ✓ Provide a "translational foundation" for the development of clinical treatments for disease (e.g. drug targets, specific diagnostic studies, etc)

Novel Aspects of the MAPP Research Network: An Expanded Scope

- ✓ Multidisciplinary and novel scientific approaches to go beyond the "one organ-one disorder" view
- ✓ All research will focus on questions of clinical relevance
- ✓ Promote opportunities for new investigators and experienced investigators from diverse disciplines to introduce new insights and directions
- ✓ Provide initial and continuous interaction of basic, translational and clinical research studies/investigators
- ✓ Promote highly collaborative studies across the MAPP Research Network to synergize efforts/speed progress

Scientific Priorities of the MAPP Research Network

Disease Phenotypes for Urologic Chronic Pelvic Pain Patients: Identify physical/anatomical, physiological, psychosocial/psychological characteristics associated with IC/PBS and CP/CPPS and relationships with potential co-morbid disorders, such as IBS, fibromyalgia, CFS, vulvodynia, and migraine headache.

Targeted Epidemiological Studies of Relevant Patient Populations: Examine natural history of IC/PBS and CP/CPPS inpatient cohorts to identify risk factors for disease predisposition, development, exacerbation/remission, and progression.

Basic Cellular, Molecular, and Bi ochemical Studies:
Address the underlying pathology of IC/PBS and CP/CPPS, including the fundamental basis of disease development and progression using in vivo and in vitro assays, cell lines, animal models, etc.

Some RFA Key Dates/Facts

Initiative Reference Number: RFA-DK-07-003

[Clarification in the NIH Guide: NOT-DK-08-003]

Letter of Intent: December 17, 2007

Receipt Date: January 9, 2008 (no extensions)

Earliest Start Date: July 1, 2008

Funding Period: 2008-2013 (5 years)

Funding Level: \$7.5 Million / year

Award Type: Cooperative Agreement (U01)

See RFA for weblink to view updates, FAQs, etc

MAPP Research Network Organization

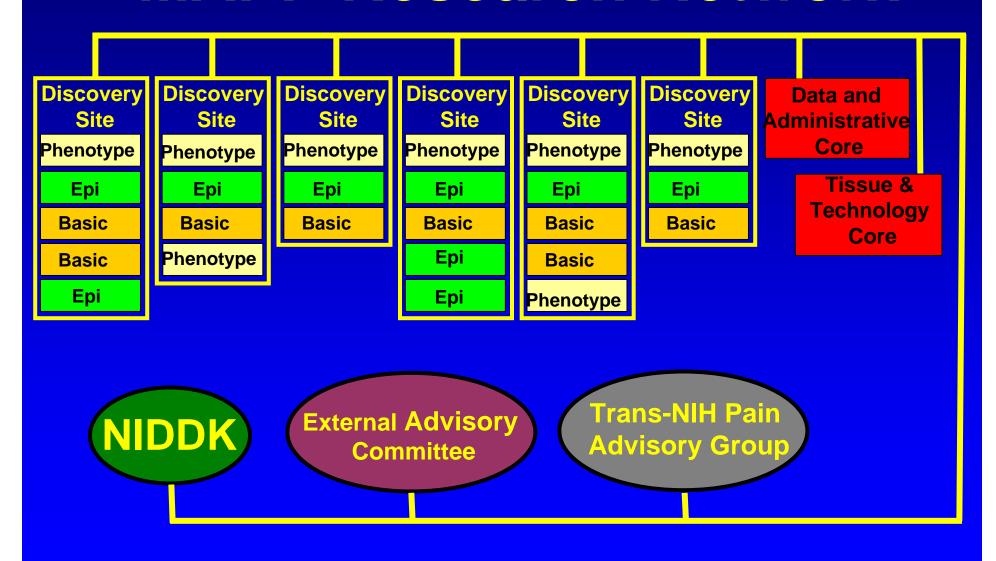
Six highly interactive research Discovery Sites (U01s)

- \$1 million in Total Costs per year for five year funding period
- Director or two Co-Directors with appropriate expertise
- Three to five individual Research Projects with Project Leaders
- Each of the three MAPP research priorities <u>must</u> be addressed in at least one Project (hence three Project minimum)
- At least one Project must propose potential <u>trans-MAPP</u>
 Network efforts
- Small Cores may be proposed, but must be justified

Two shared Cores Sites (U01s):

- (1) Data Coordinating/Administrative Core
 - \$750,000 in Total Costs per year for five year funding period
 - Director or two Co-Directors with appropriate expertise
 - Oversee Ancillary Projects Program
- (2) Tissue Analysis and technology
 - \$750,000 in Total Costs per year for five year funding period
 - Director or two Co-Directors with appropriate expertise

MAPP Research Network



Highlighted MAPP RFA Q/As

- Q. Can I participate on two or more MAPP RFA applications?
- A. YES, provided you adhere to NOT-DK-08-003 in the NIH Guide.
- Q. Can I submit a separate application (e.g. R01) on my MAPP application project at the same time as the MAPP U01?
- A. NO, this may jeopardize acceptance of your MAPP application.
- Q. How do I propose a Trans-MAPP Project without knowing what other sites will be funded?
- A. Your proposed trans-MAPP Network Project(s) should include efforts that you envision benefiting from the collaborative effort of multiple MAPP Sites. You do not need to name specific MAPP Discovery Site applicants. All proposed Trans-MAPP Projects will be evaluated when the group begins to meet and high priority study designs will be adopted by the Network.

Highlighted MAPP RFA Q/As

- Q. What is the application format, page numbers, etc?
- A. MAPP RFA U01 applications will follow the general format as NIDDK P01 applications (see the RFA for details and the listed P01 website for specific page limits, etc).
- Q. Does a MAPP Discovery Site have to focus on both IC/PBS and CP/CPPS?
- A. The application must focus on either or both IC/PBS and CP/CPPS. The application must also address the relationship between IC/PBS and/or CP/CPPS with possible co-morbid conditions.
- Q. Can pilot clinical trials/interventions be part of a proposal?
- A. NO, the MAPP RFA is NOT soliciting clinical intervention/treatment efforts (we hope to lay the foundation for such future efforts).