

Urology Interagency Coordinating Committee (UICC)

Monday, June 25, 2012 1:00 p.m. - 4:00 p.m. 6707 Democracy Blvd. Room 701 A-B Bethesda, MD

Meeting Minutes

Meeting Attendees:

R. Alexander (VA)

L. Begg (ORWH/NIH)

C. Best (DOD/CDMRP)

E. Duggan (NIDDK/KUH)

P. Eggers (NIDDK/KUH)

D. Hoshizaki (NIDDK/KUH)

E. Hoff (NIDDK)

K. Huntley (NCCAM/NIH)

Z. Kirkali (NIDDK/KUH)

S. Moss (NICHD)

C. Mullins (NIDDK/KUH)

M. Murthy (NIA/NIH)

E. Parrott (NICHD/NIH)

L. Porter (NINDS/NIH) (on phone)

T. Rankin (NIDDK/KUH)

R. Star (NIDDK/KUH)

D. Schwartz (CMS)

R. Wiederhorn (FDA)

Y.Xie (NIDDK/KUH)

Welcome and Introductions

Dr. Kirkali opened the meeting and welcomed attendees to the Urology Interagency Coordinating Committee meeting. Dr. Kirkali presented information about public law 99-158 and the importance of interagency coordinating meetings. Dr. Kirkali then presented background information on the UICC including history and committee goals and objectives. Dr. Kirkali directed meeting participants to the agenda.

Federal Urology Research Coordination: Why? What? How?

Dr. Star reiterated the importance of interagency collaboration and how ideas from meeting participants can enhance current research directions within the NIH and form partnerships among agencies. NIDDK is also looking for feedback from other agencies about how the Institute may lend resources and/or expertise to initiatives and efforts within other agencies. Projects of interest include: unidentified areas of need, areas of research within benign urology, etc. Dr. Best noted that it takes time for good interagency collaboration; one of the committees she participates in meets twice a year. Dr. Alexander asked what percentage of the overall KUH budget was devoted to urology. Dr. Star noted the KUH overall budget and the portion of the urology budget.

Symptoms of Lower Urinary Tract Dysfunction Network (LURN)

Dr. Kirkali discussed a urology Funding Opportunity Announcement from KUH: The Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN). Dr. Kirkali discussed the importance of measurement and finding universally accepted measurement tools for disorders such as urinary incontinence in both males and females. Storage symptoms and quality of life issues for these patients are also highly relevant and pertinent; current symptom measurement tools do not accurately capture or enable assessment for these issues within the context of research. Dr. Kirkali also noted efforts by the PROMIS initiative.

LURN, a U01 RFA, is designed to better define the phenotypes of males and females with symptoms of lower urinary tract dysfunction (LUTD). This RFA supports the development of a cooperative research network (Symptoms of Lower Urinary Tract Dysfunction Research Network, or LURN) to develop and qualify symptom-based instruments to measure early, late, transient, and persistent symptoms both in males and females, and to better define the phenotypes of men and women with symptoms of LUTD. Dr. Kirkali described the design, organization structure, and budget for this initiative.

Participants asked about level of response to the RFA; Dr. Kirkali responded that many strong applications were received. Participants also asked how the awards were distributed; Dr. Kirkali responded that the review will take place on July 16, and approximately 4 sites would receive awards.

Discussion

Dr. Star asked the group for feedback about the science and design on this initiative. Participants provided the following feedback:

- Question about slide 13 data. Participants noted that slide was very informative and striking.
- Question about response from AUA. Dr. Kirkali noted that AUA has been highly involved in this process. The AUA officers attended the MOMUS meeting, which laid the groundwork for developing this RFA.
- Participant asked how drug companies would respond to approval of new measurement device by the FDA. Dr. Star noted that industry was involved in the AUA Symptom Score, and were aware of the LURN project.
- Question about what the FDA is seeking in terms of measurement tools as they relate to drug approval. Dr. Wiederhorn responded that the FDA would like to see a PRO for assessment of lower urinary symptoms.
- Question about developing the phenotyping protocol. Dr. Mullins discussed how efforts within the MAPP Network are working to develop and define the phenotyping.

Dr. Star asked for feedback on administering this type of large project:

Participants noted the need to develop a plan to keep PIs on track and collaborating. Drs.
 Mullins and Hoshizaki noted efforts within the MAPP and GUDMAP projects to establish such
 efforts and reach collaboration goals. Participants noted that it would be helpful to have a
 process for modifying or removing underperforming Centers/PIs in place before awards are
 made. It was also suggested that it would be helpful to establish milestones for each
 Center/PI prior to award. Dr. Alexander mentioned that VA is a great resource for such an
 effort and collaboration can be established.

Dr. Star noted that, in the coming months, meeting participants will be contacted for external advice and steering committee assistance.

Dr. Alexander inquired what NIDDK would also fund if budget was not a concern. Dr. Alexander suggested potential collaboration on topics such as: diabetes, inflammation and the prostate, stone disease, and effects of testosterone therapy on aging men. Dr. Begg noted the need for more initiatives in incontinence and obesity.

Dr. Hoshizaki noted difficulty recruiting productive young urology PIs as well as pipeline/training issues for young PIs within this community. Participants noted concerns using the U01 mechanism for established PIs. Dr. Hoshizaki noted efforts within GUDMAP to control concerns.

Dr. Star noted the need to locate a urologic science forum to assist NIDDK in identifying important topics: Dr. Best suggested creating a think tank meeting that includes basic, translational, and clinical researchers.

Agency Updates

- Dr. Christine Huntley from NCCAM—Noted that NCCAM external research committee needs
 more oversight. NCCAM is working to identify sites that need to be monitored and evaluating
 the level at which sites need to be monitored. Dr. Huntley also noted that the new Diagnostic
 and Statistical Manual of Mental Disorders should be released in the next year. There is a
 staffer in her office working on the PROMIS initiative.
- Dr. Murthy from NIA—Noted that his Institute is interested in basic science and clinical biology, particularly in the area of androgens. Also, NIA is looking to fund research on tests for overactive bladder.
- Dr. Begg from ORWH—Noted a-new initiative for an administrative supplement program for FY 14. ORWH areas of interest include sex differences and women's health. Mechanisms could include RPGs.
- Dr. Best from DOD—Noted areas of interest/potential collaboration for urology include prostate cancer and general administrative experience sharing.
- Dr. Parrott—Noted areas of urologic interest include pelvic floor disorders and studies on overactive bladder.
- Dr. Schwartz from CMS—Noted that he was not aware of any research or ongoing urology projects. However, Dr. Schwartz noted the need for greater urologic presence in hospitals and nursing homes. Dr. Eggers discussed the UDA project.
- Dr. Alexander from the VA—Noted that he is not familiar with urologic research efforts at the VA. Dr. Alexander will explore this topic prior to the next UICC meeting.
- Dr. Moss from NICHD—Noted areas of urologic interest include male infertility as it pertains to the general health of males (obesity, cancer, etc), transgenerational transmission related to epigenetics, and female infertility problems such as endometriosis, stone disease, etc.
- Dr. Rankin from NIDDK—Noted urologic initiatives such as the K12 grants that support urologic research opportunities for scholars. Dr. Rankin also noted an upcoming urologic complications of diabetes meeting.
- Dr. Hoshizaki—Noted a urology initiative to convert O'Brien urology centers grants from P20s to U54s. Also, the ongoing Murine Atlas of Genitourinary Development (GUDMAP) project, a consortium of laboratories working to provide the scientific and medical community with tools to facilitate research.
- Dr. Wiederhorn from the FDA—Noted urologic areas of interest included work on PROs, overactive bladder, premature ejaculation, define IC and urgency.
- Dr. Star from NIDDK—Noted a potential area of collaboration among agencies could be the NIH biomarker consortium.

Meeting Adjourned