

**National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)  
Workshop on Advancing Urologic Science and Career Development**

**February 15–16, 2007  
Key Bridge Marriott Hotel  
Arlington, VA**

**Meeting Summary**

**I. WELCOME AND OPENING REMARKS**

**Welcome**

*Griffin Rodgers, M.D., Acting Director, NIDDK*

Dr. Rodgers welcomed attendees to the workshop and thanked them for coming. He said that urologic diseases are costly; approximately \$1 B is spent in treatments, including for urologic incontinence, which affects 13 million people (mostly women) and urinal stones. Congress has expressed an interest in seeing urology research accelerated from basic science to translation and into practice. It is expected that this workshop will help NIDDK shape its direction in promoting and conducting urology research. The field is faced with research and cultural issues, and NIDDK must conduct its research under a flat—and even declining—budget. Dr. Rodgers asked participants to contribute actively during the workshop to help NIDDK place its funds appropriately to accelerate urology research. He invited participants to send comments to him by email.

**Introductions and Opening Remarks**

*Robert A. Star, M.D., Acting Director, Division of Kidney, Urologic, and Hematologic Diseases (KUH), NIDDK*

Dr. Star asked participants to introduce themselves briefly. He explained that this workshop allows NIDDK to obtain different perspectives on how to encourage research in urology. He thanked Dr. Debuene Chang, KUH Program Director, and other KUH staff for organizing the meeting.

Benign urologic diseases have a significant public health impact. In 2000, for example, 8 million physician visits resulted in a direct cost of more than \$1.1 B. Diabetes, obesity, and metabolic syndrome may increase the progression of benign urinary-associated symptoms. Direct costs for urinary incontinence in 1995 totaled \$12.4 B for women and \$3.8 B for men. Chronic prostatitis, urolithiasis, and erectile dysfunction also are prevalent. The growth rate of health care needs and expenditures requires accelerated discoveries and clinical validation. There are many unsolved public health problems. Dr. Star noted that this workshop would provide an opportunity to discover ways to address these needs.

Dr. Star described NIDDK's core missions. NIDDK aims to maintain a vigorous investigator-initiated research portfolio and to support pivotal clinical studies and trials. To encourage

careers in research, NIDDK works to foster exceptional research training and mentoring opportunities as well as preserve a stable pool of talented new investigators. It also ensures knowledge dissemination through outreach and communications.

Dr. Star next provided a macro overview of NIDDK's support of research in urologic disease. During the period of National Institutes of Health (NIH) budget doubling, NIDDK's funding of urologic disease studies increased; however, it now is declining at a greater-than-expected rate. The percentage of KUH funds allocated to the Investigator Initiated (R01) mechanism has decreased, as has total urology funding. Current funds support various grant mechanisms, particularly Cooperative Agreements (U01s) and R01s.

Dr. Star noted that 25 to 30 percent of NIDDK's dollars that are spent in urology are allocated to large projects. The U01s include: Urologic Diseases in America (UDA); Urinary Incontinence Treatment Network (UITN); Chronic Prostatitis Clinical Research Network (CPCRN); Interstitial Cystitis Clinical Research Network (ICCRN); RAND Interstitial Cystitis Epidemiology (RICE) Study; Interstitial Cystitis Genetics Study (ICGS); Boston Area Community Health (BACH) Survey; Complementary and Alternative Medicine for Urological Symptoms (CAMUS); Minimally Invasive Surgical Therapies Treatment (MIST) Consortium; Randomized Intervention for Vesicoureteral Reflux (RIVUR) trial; and Genitourinary Development Atlas (GUDMAP).

A modest decrease has been seen in funding for all three types of R01s: new (Type 1) for both established and new principal investigators (PIs); competitive (Type 2); and non-competitive (Type 5). The rate of submissions of urology applications for competing R01s (Types 1 and 2) is seen as constant, but the new investigator R01 applications are decreasing.

NIDDK's KUH has a lower application success rate than NIDDK overall, because most urology applications are reviewed in one study section. The rate is defined by the number of awards given per year divided by the number of applicants. The KUH is watching the payline closely. Regarding individual training awards (F grants) and career awards (K grants) in urology, the number is decreasing for F grants but remains constant for K grants.

NIDDK has heard worrisome statements about the state of urology careers that might dissuade researchers from entering or staying in the field. These include that new and established investigators are not attracted to urology research and that significant cultural barriers exist that impede training and the conduct of urologic research. There also appears to be a lack of interaction between urology M.D. and Ph.D. researchers and between basic and clinical urology research. Basic researchers ignore clinical questions, and basic findings are not translated into clinical studies or trials. Another comment is that new and established urology researchers do not compete successfully for NIH funds.

Dr. Star mentioned special urocentric issues. It is harder, for example, to determine the pathophysiology of symptomatic diseases. The field of urology must interact with surrounding disciplines. M.D. urologists are surgeons, are paid as surgeons, and have the time demands of surgeons. In addition, there are few competitive renewal applications (Type 2s), and there is a financial incentive to study prostate cancer rather than benign urologic diseases.

For the long term, NIDDK hopes to help create a vibrant and sustainable urology research and training community that efficiently translates basic research and clinical discoveries to solve critically important benign urology public health needs. To reach this goal and solve what is a systems problem, a cooperative effort is needed on the parts of urology departments, professional societies, and NIH. This meeting provided a beginning for such collaboration. The workshop goals were to: (1) develop a clear and shared vision of where the field should be; (2) identify issues and underlying drivers; (3) identify and discuss any roadblocks or gaps; (4) generate an action plan for how the field should evolve in several areas; and (5) develop measures to evaluate progress.

Two scenarios for the future of urology are likely: (1) Academic urology departments offer training and career slots to support the discovery of core research knowledge, fund multi-disciplinary projects, and interact with clinicians and other disciplines to develop tool sheds; (2) A multi-disciplinary project includes urologists working with other disciplines to promote training and career slots; together, all parties develop tool sheds.

Dr. Star identified four areas needing consideration to be addressed by the workshop breakout groups: (1) recruitment, retention, and career development for urologic scientists (People); (2) competitive urology basic and clinical research project development (Projects); (3) creation of an environment for urology research and training (Places); and (4) development of a technical/methodological foundation for urological science (Tools). He explained that Day 1 would set the stage with descriptions of the focus groups and goals and the identification of problems and potential approaches. The breakout groups would summarize their main ideas to the plenary group. Day 2 would focus on developing short- and long-term action plans, including specific responsible parties and metrics to be presented to the plenary group for discussion. NIDDK anticipates several deliverables that would result from the workshop discussions, including a more unified vision of urology research, white paper(s), specific action items that delineate first steps and specific responsible parties, an evaluation plan, and further community input. A follow-up meeting is expected to occur within 1 year.

Dr. Star thanked the American Urological Association (AUA) for sponsoring the workshop attendees' dinner on Day 1.

## **II. VISION STATEMENTS FOR PLANNING EFFORTS AND VIEWS FROM THE UROLOGY COMMUNITY**

*John D. McConnell, M.D., University of Texas Southwestern Medical Center, Dallas, TX*

*Anthony Schaeffer, M.D., Northwestern University, Evanston, IL*

*Darracott Vaughn, M.D., Cornell University, Ithaca, NY*

### ***Advancing Urologic Science: An Academic Medical Center Perspective***

Dr. McConnell provided an academic medical center perspective of the current state of urologic science. To effect changes in the research industry, four steps are necessary: (1) define the current state; (2) define the desired future state—that is, a detailed description of what “Urologic Science” could look like in 5 to 10 years, encompassing people, priorities, tools, collaborations,

and other considerations; (3) define the known reasons for the gap between the current and future state—these usually can be classified as barriers to change (negatives) and lack of catalysts (positives); and (4) develop strategies to close the gap.

In the urology field, creating a research experience in residency/fellowship presents a challenge—even for premier institutions—and training grants are not helpful for surgical specialties. The transition from junior investigator to an established, independent investigator has a high failure rate. Many grants funded through request for applications (RFAs) are never converted to R01s. Moreover, it is difficult to recruit talented young people into academic urology. NIH perceives that it is not receiving an adequate return on investment, and the urology research community perceives that NIH is not supportive of its unique needs. There is confusion about priorities, particularly as to whether there should be an increased output of quality clinical and basic science in urologic disease or increased funding for urology departments. Millions of dollars have been spent on the study of “diseases” that have not been phenotyped adequately; this presents a “cart before the horse” situation. Additionally, the study section expertise has improved but remains challenging. Dr. McConnell concluded that the quality of grant proposals and underlying science simply are not what they should be.

He explained that, from an academic medical center perspective, these challenges are not unique to urology. Most surgical specialties are dealing with the same issues, including:

- The transition from fellowship to faculty;
- The high variability of fellowships in preparing young surgeons for academic careers (as opposed to learning advanced surgical techniques);
- The lack of formal training in clinical research;
- The inability to develop and foster collaborations with investigators in other departments, especially the basic sciences;
- How to establish and fund protected time;
- Departmental versus institutional organization of clinical research or clinical trial units;
- Department chairs often do not understand the fundamentals of how to mentor young, research-oriented faculty because they themselves were not mentored; and
- Salary expectations do not mesh with the reality of funding; only departments with substantial endowments are able to meet such expectations.

Other insights from the academic medical center perspective include that K08 grants are not meeting the needs of most surgical specialties, particularly with regard to salary and surgical skill development. Moreover, organized urology has not stepped forward, as have other academic fields, to provide funding for early faculty development. More research (and patient care) is being organized across traditional departmental lines, and the Cancer Center paradigm is being extended to many other areas. Central resources, such as tissue procurement and serum banks, often are driven by specific disease interests rather than a more comprehensive approach. Many departments, divisions, and individual faculty that either are “interested in research” or are told by their dean that they are lacking in research generally try the “let’s hire a Ph.D.” approach, which almost uniformly fails. Dr. McConnell suggested that an investigator hired into a full-time research faculty position should be qualified for a dual appointment in the basic science and urology departments and that there should be a critical mass of investigation occurring in the

department. Otherwise, a collaborative model with scientists in other departments is more likely to succeed. Finally, academic pharmacy and therapeutics committees continue to struggle to understand clinical investigator issues.

Dr. McConnell shared several “editorial” comments. One was that urology would be stronger if it focused on the quality of the science rather than the quantity of funding. In addition, organized urology should partner with NIH to provide career development support between an individual’s receipt of a fellowship and the first grant. There is a need for a “surgical” K08 that is rational. Fellowships need to be designed with academic research careers in mind, including formal clinical and translational research training. Moreover, support for residency research experience is critical, and some of this should be patient-oriented research. Another comment was that grant funding mechanisms should catalyze collaborative team science within institutions. Program projects and center grants with cutting-edge science from top scientists should be teamed with translational research-oriented urologists. Dr. McConnell suggested that the O’Brien Kidney Research Centers (O’Brien Centers) concept should be expanded to 12 to 15 institutions, and that it should have a structure similar to NIH’s Clinical and Translational Science Awards (CTSA) consortium—that is, with no single specific disease focus required. Strong basic science components built through collaboration, a career development portion for young researchers, and unrelated projects also should be developed.

#### ***AUA Foundation (AUAF): Research Task Force***

Dr. Schaeffer described five critical issues that the AUAF’s Research Task Force is considering: (1) Federal policy and funding encompasses U.S. Agencies and Capitol Hill, as well as patients, physicians, and researchers; (2) a robust National Research Agenda is needed; it requires broad input and consensus from all stakeholders and could provide a foundation for other activities; (3) a strategy should be implemented to encourage the development of young scholars; it should attract quality people, be adequately funded and adopted by all players, and effect a culture change; (4) a research scholars program should allow greater flexibility and be implemented earlier in the academic continuum, identify areas of study, and be linked to outcomes; and (5) improved dissemination of information should create better links among those working in research, education, and practice, as well as increase communication among leaders.

Dr. Schaeffer offered several recommendations:

- Streamline and redefine the Research Council;
- Adopt a multidisciplinary approach;
- Increase interactions with NIH;
- Emphasize the importance of research to the field of urology;
- Change the culture;
- Strengthen the network of researchers;
- Coordinate public policy efforts;
- Seek innovative ways to direct funding; and
- Develop a National Research Agenda.

### ***Strategy Planning: Urology Issues and Stresses across the Academic Industry***

Dr. Vaughn explained that there is stress throughout the academic industry, not just in urology. Innovative strategies will be needed to “think outside the box” and adopt a new paradigm of working together and becoming more interdisciplinary. An example of this is a dean who ensured that all of his departments worked together by making them share the laboratory facilities. Strategy planning also must consider the issue of salary structures; there is stiff competition across the country in various disciplines. Additional issues include the source of income (approximately 40% of income must come from outside clinical care); the number of schools that are converting to a 5-year program; and the small number of students who pursue the academic career path. There are residency concerns, and junior faculty members are faced with large debts. A joint interdisciplinary group should address recruiting researchers; they would be aided greatly by a blueprint. Moreover, most faculty members are affected by mentoring and protective-time issues. The roles of the clinical centers (including educational and mentoring components on how to conduct basic and clinical research), NIH, and the AUA also are important. The relationship between the AUA and NIH could be strengthened.

### ***Plenary Discussion***

A discussion ensued regarding the inclusion of non-urologists in the urology field. One participant asked whether the AUA has made an effort to include the renal community at large, and whether its grants were awarded only to urologists or to others who might conduct, for instance, outcomes research. Urology departments can adopt an interdisciplinary approach, such as a co-investigator research center concept.

All fields of surgery face the same issues as urology with regard to salaries. Both research and practice should be valued, but there is a significant discrepancy between salaries.

The fostering of young researchers was discussed at length, including the available forums in which they can present their research. Young scientists often do not remain in research because of their debt. They need more support because they have had the least amount of training. It is important to recruit people early—even at the undergraduate level—particularly for future Ph.D. candidates. The opportunities for discovery in urology should be emphasized; the young are presented with negatives about rather than enthusiasm for the field. Urology is a great opportunity, and innovation and creativity should be rewarded. Mentoring the young is problematic because no one has been taught how to mentor. Students need to learn how to perform critical reviews, write papers, and link data to current research, as well as how to work in the laboratory.

NIH’s review study sections could be improved. The same grant application currently would receive very different treatment from two different study sections. The quality of the reviewers is paramount, and senior investigators should be recruited to assist. In response to this issue, Dr. Rodgers told attendees that NIH held an emergency Institutes and Centers (IC) Council Meeting on this topic to discuss the length of review time and the quality of reviewers. NIH is seeking creative ways to expedite the process without sacrificing the attention paid to the quality of the applications.

### **III. UROLOGIC SCIENTIST RECRUITMENT, RETENTION, AND CAREER DEVELOPMENT (PEOPLE)**

*Jeanette S. Brown, M.D., University of California at San Francisco, California*

*Larissa Rodriguez, M.D., University of California at Los Angeles, California*

#### **A. Focus Group Goals**

Dr. Brown described the Association of American Medical Colleges' (AAMC) Task Force on Clinical and Translational Research's multidisciplinary team approach to the recruitment, retention, and career development of urologic scientists. A cartoon of a leaky pipeline illustrated the attrition of trainees in the continuum of clinical research. Current challenges to accomplishing this include high educational debt, low clinical revenues, a flat or reduced NIH budget, and decreasing institutional resources. In addition, young researchers can find it difficult to balance family and work. To find a clear path to academic advancement, the task force is working to determine how best to recruit, train, nurture, and sustain the next generation of clinical and translational physician-scientists. The intent is to accelerate training through a comprehensive restructuring of the programs and to have researchers fully trained and independent by age 32 to 34. The training would include a master's degree program and 2 to 3 years of mentored research.

Junior faculty members need proper training, mentoring, and team support. In particular, it is recommended that they be given 3 years of protected research time following their master's degree and career development awards (CDAs), as well as dedicated space. They should be able to devote at least 50 percent of their time to research.

To encourage urology research, the urology community must think outside urology. The AAMC/CTSA "Research Incubator" diagram illustrates how the components of the research continuum (i.e., curriculum, translation incorporated early in one's training, senior mentorship and multidisciplinary teams, and research infrastructure resources) must span all research levels, including students, residents, fellows, and junior- and mid-level faculty. She explained the needs of basic science researchers, both M.D.s and Ph.Ds: they should hold a research/post-doctoral fellowship for a minimum of 2 years; be allowed protected time (for a minimum of 2 to 3 years) as junior faculty; hold a joint appointment with the science department; develop a path to independence; and foster interdepartmental collaborations. The M.D. scientist should be allowed "shorter" Ph.D.-granting programs and have Ph.D. and physician-scientist mentors. The Ph.D. basic science researcher should include translational work early in his/her training and have mentors who include Ph.D.s and urology physician-scientists.

It is important to start recruiting medical and Ph.D. students for research early in their careers. Urology residents should be encouraged to pursue a basic or clinical research career. Ph.D. students can be attracted through tenure-track positions, joint appointments that allow access to Ph.D. students, and a clear path to independence.

To create and enact a strong urology career vision, all major stakeholders—including urology departments, institutions, specialty boards, AUA, foundations and pharmacology entities, and

NIH—must work together to build strong urology research programs for residents and fellows, as well as a clear research career development paths for junior urology faculty.

Dr. Brown explained that the Breakout Group discussions for “People” would include culture changes, recruitment and retention, successful research career paths, and barriers. It also would identify first steps and responsible parties.

### ***Plenary Discussion***

There is a dearth of Ph.D. candidates in cancer biology and other sciences, but exposure from top scientists might serve to attract students. Age and other factors might be a deterrent if there is extended training required for medical school and Ph.D. training. One way to increase the number of Ph.D. residents might be to tie the residency program to research to help create first-class science.

### **B. Identification of Problems and Potential Approaches**

The “People” Breakout Group discussed problems involved in the recruitment, training, and retention of students, residents, fellows, and faculty in urology research. Dr. Rodriguez presented these ideas to the Plenary Group at the end of Day 1.

An important point discussed throughout the session was the lack of communication between the AUA, chairs of urology departments, and the American Board of Urology (ABU). Research goals and the need to collaborate with non-urologists also were identified as important problems and discussed extensively.

To recruit medical students and help them develop an appropriate way of thinking, research courses and exposure to research are needed. Residents in general are available, but the opportunity to enter research needs to be presented to them, and a shorter duration of training and better funding would make it more attractive. Specifically for urology residents, the urology community should determine the number of clinician-scientists that are needed and whether a year of research helps develop better doctors (18% of programs require 1 year of research). It was suggested that urology residents receive further research training and write a grant proposal during their clinical years; this could occur in a non-urology laboratory or clinical research group and would help short-track their training time. The Breakout Group asked a number of questions regarding urology fellowships, such as the necessity or possibility of short-tracking them, the possibility of obtaining CDAs during that time, and the commitment of a faculty position; potential problems are board requirements, the training length, and the current salary structure.

The Breakout Group recommended that the clinical and research training and board requirements be restructured, the laboratory experience be better structured, and the academic institutions adopt a multidisciplinary approach. It was noted that urology departments are too small; and it was suggested that they implement weekly meetings for faculty, research residents, and clinical residents. A junior faculty position would ideally include a K08/K23 grant with mentored training. In addition, the differences in pay scale between clinician-scientists and full clinical faculty should be minimized.



To advance urologic research, more Ph.D. and basic scientist input is needed. This could occur through increases in collaborations, tenure track positions in urology departments, and joint appointments with basic science departments. The Breakout Group agreed that, “If you do not own the basic scientist, the basic scientist is not going to own you.”

To recruit Ph.D. researchers into urology departments, the departments should provide funding and resources, but the researchers also could be based in basic science departments. Researchers should be independent faculty members, not researchers who work for a clinician. Co-appointments might help offset the high costs that are associated with this.

Recommendations for faculty recruitment included a salary guarantee, necessary equipment, a technician or clinical research assistant, space in which to work, and a budget for operating the laboratory or biostatistician support. The Breakout Group strongly agreed that these requirements should be guaranteed for a minimum of 3 years.

Collaborations can be effective, but the cultures in urology and basic science departments need to change, core/critical mass urology research with grants that originate in urology departments is needed, and the issue of indirect costs must be addressed. Indirect costs could be used to encourage basic departments to collaborate, and the departments could be measured by the number of their collaborations/grants. Finally, a “Take a scientist to work day” should be initiated to invite basic scientists (i.e., postdoctoral students) and tumor boards to visit.

The Breakout Group recommended that NIH increase the number of K12 awards (i.e., training grants to urology departments or spots in the Roadmap K12 program for urologists). The T32 vehicle perhaps could be used to fund research fellows and reduce the large attrition rate; goals and metrics could be established to help researchers achieve a K award by Year 2. NIH could assist with influencing trainees’ perceptions of R01 funding success as well as work to expand the loan repayment program.

The retention of medical and Ph.D. students and researchers could be abetted by improved mentoring—including frequent reviews and meetings with departmental mentors—and an early review of grants by a departmental committee before the grants are submitted—to avoid triage.

Regarding the AUA, it was noted that Ph.D. researchers cannot obtain full membership in the AUA. AUA’s policy of awarding grants only to urologists and not to other scientists who conduct urology research should be revisited. Other issues raised include: the percent of AUA budget that is dedicated to research; the need for more podium presentations on basic science research at AUA conferences; the need to increase and make more visible the interactions between the Society for Basic Urologic Research (SBUR) and the AUA; NIH’s participation at the AUA’s Annual Meeting, such as by offering a grant writing workshop or providing opportunities for support; and a course on career development at the AUA.

### *Specific and Additional Comments*

During the discussion, participants offered additional or more specific comments, including the following.

Basic medical departments conduct a large amount of research because they have a healthy number of researchers. The most successful programs require trainees to write a grant application during their clinical time, and the application is reviewed by the department. The grant application is similar to a scope of work, and the residents are exposed to research early.

A lengthy discussion ensued about the need for fellowships and the requirement to devote 1 or more years to urology research before a student has selected or refined his/her career field. Overall, the Breakout Group concurred with the idea of restructuring or decreasing the clinical training time and board certification requirements to allow for research training and success in a timely fashion. Many other fields are expediting or short-tracking training. The current fellowship structure and the Urology Boards' requirements may need adjustment to streamline training and improve recruitment and retention. One flexible approach might be to allow the last year of residency to function as a fellowship. A participant questioned the value of fellowships, noting that under the current structure they do not facilitate career development.

An anti-research climate exists in urology, which is manifested by a question frequently asked: Will research make a better doctor? Other medical fields are more appreciative of research.

In the "ideal world," the salaries of academic urology researchers and urology clinicians should be equivalent. The salary differences will never be eliminated, but certain academic values could be promoted to attract students, residents, fellows, and PhD students and postdoctoral students.

To attract non-urology Ph.D. investigators, it is necessary to collaborate with basic science departments or recruit basic science faculty into tenure-track positions in urology departments (who are jointly shared with basic science departments). Early outreach is necessary to recruit the best and brightest candidates.

Collaborations with PIs would involve training clinicians who appreciate basic researchers and negotiating with institutions regarding the ownership of grants. This requires substantial open communication.

NIDDK has a special K award announcement to encourage urologists to work with basic scientists. The expansion of T32 awards also was discussed; the past attrition in urology T32 awards likely was due to funding issues and internal pressures from academic institutions that had weak guidance or leadership. A junior investigator who has received a K award should be monitored and supported by his/her department and institution through all stages of the grant; mentorship helps tremendously.

The AUA should offer podiums for basic researchers, rather than just poster sessions. Additionally, the AUA should encourage basic research; currently, the sessions emphasize

clinical work. The SBUR could increase the scientific profile of the AUA's annual meeting and promote better integration of basic science.

A number of professional societies schedule their annual meetings simultaneously but in different locations, which prohibits members from attending more than one society's meeting and thereby decreases interaction and collaboration among disciplines.

### ***Plenary Discussion***

Various opinions were expressed regarding the inclusion of a Ph.D. basic scientist in urology departments, ranging from caution about the idea to full support. If Ph.D. basic scientists are included, they should not be subordinate to clinicians but rather treated as equal partners.

An NIH mechanism to share PIs would be good. It could help sort out the monetary and credit issues surrounding ownership of co-investigator grants. Additionally, a multidisciplinary center could present a forum in which basic scientists, clinical researchers, and clinicians collaborate.

Participants offered comments about the AUA. One participant supported the idea that everyone should be able to present at AUA meetings, receive feedback, and have one's travel covered. Ph.D. scientists also should be admitted with full membership in the AUA. It was noted that NIDDK's KUH had offered to conduct a grant writing course at the AUA annual meeting, but the idea was declined.

### **C. Developing a Short- and Long-Term Course of Action**

The People Breakout Group debated various short- and long-term actions that could help recruit and retain residents in urology research careers. Dr. Brown presented the suggestions to the Plenary Group at the end of Day 2.

An important theme that pervaded the discussion was the need to think outside urology and collaborate with other departments.

A plan to recruit, train, and retain the next generation of urology researchers must be deliberate and strategic. It should involve training that is accelerated through comprehensive restructuring so that investigators are fully trained at a reasonable age, resources are available to help researchers grow to independence, and multidisciplinary teams are encouraged.

The Breakout Group next identified short-term goals for urology and non-urology stakeholders. This was followed by long-term goals that would promote successful academic urology research careers.

Urology stakeholders include physician urology scientists and numerous organizations, including the AUA, academic chairs, genitourinary (GU) surgeons, the Resident Review Committee (RRC), urology boards, and other leaders from outside organizations. Short-term goals for these groups include:

- Create a culture change, starting with a meeting on this topic, to be held within 6 months;
- Restructure programs for residents, fellowships, and junior faculty to: improve coordination, improve the quality of research and career development, increase flexibility with movement, promote short-tracking to be competitive with other disciplines, and adjust the salary structure in academic programs to minimize pay-scale differences between research- and clinical-focused faculty.
- Create an environment that values clinical and research work by: promoting training, mentoring, and teamwork; supporting junior faculty researchers sufficiently, with 3 years of protected time, adequate resources, and dedicated space; scrupulously “protecting time,” with at least 50 percent of a person’s time devoted to research.
- Increase collaboration among the AUA, departments, and institutions to: create strong training programs; improve residency training and mentoring; develop a research fellowship program; assist fellows and junior faculty in obtaining CDAs; provide seed money for early research; encourage pilot studies, secondary data analyses, and ancillary studies; and incorporate metrics and evaluation criteria.
- Improve faculty retention by developing a rational, efficient organization that uses a clear, consistent reward system and offers adequate protected time, good infrastructure for research, and some clinical or other “hard” income.

Short-term recommendations to expand urology research to encompass non-urologist physician scientists and Ph.D. scientists include the expansion of AUA membership, meetings, and funding to the broader scientific community. Other suggested goals are to: increase the number of tenure-track, independent positions, particularly through training and mentoring programs; award joint appointments in urology, basic science, and clinical research departments; and promote multidisciplinary teams and research centers of excellence. Finally, the urology community would be helped by a “Take A Scientist To Work” day.

The Breakout Group identified several short-term goals for NIH. These included increasing the number of T32, K12, and K24 grants for institutions that provide a CTSA-type of training and infrastructure. NIH also could expand its loan repayment program and increase the number of RFAs and requests for proposals (RFPs) in urologic areas.

For AUA leadership, the Breakout Group recommended the following goals:

- Define AUA’s research mission;
- AUA should take a leadership role to organize now;
- Decide what percentage of the budget should be dedicated to research;
- Expand support for resident training in research;
- Expand research presentations by residents, fellows, and postdoctoral researchers;
- Add more workshops on research skills;
- Expand rewards for scientific endeavors;
- Expand NIH participation at meetings; and
- Participate in study sections.

Long-term goals that would ensure successful academic research careers require active leadership from stakeholders. One aim is to create an environment that expands interdisciplinary

research and research careers through training and career development. It also is important to invest in researchers and research. Two additional goals are to: (1) identify centers of excellence that provide research training and resources; and (2) adopt a systems-disease approach.

### ***Additional Comments***

During the discussion, participants offered additional or more specific comments, including the following ideas:

Thoracic surgery was discussed as a model for restructuring a training program. The boards, for instance, examine programs but do not set standards or structure them.

The most effective way to recruit the most promising students, residents, and fellows is to identify them early and encourage them to enter the field.

We do not know how many researchers are enough, but we should continue to work toward the goal of increasing the climate of research in urology.

In approximately 6 months, the urology community leaders, including the AUAF, should meet to design a plan to short-track the training for urology residents.

Departments should mandate participation in study sections. It is important to recruit experienced people with broader views. If AUA leadership supports vigorous participation, recruiting scientists of stature into study sections will be much easier.

The urology community needs to adopt a recruiting attitude. No one appears to be investing in the growth of urology careers.

Department chairs should be asked to develop plans for collaboration between clinician and basic science researchers and training trainers (i.e., mentors). The goal should remain to advance knowledge in urology.

### ***Plenary Discussion***

The first step is to bring the major stakeholders together in the next 6 months to work on forming a research-oriented community and change the culture. The plenary group agreed that the AUA is the most likely candidate to spearhead this effort.

The success of individual research careers usually is dependent on the amount of personal attention given by the department chair. Separate training tracks should be developed for Ph.D. researchers, urology surgeons, and others.

We should not forget the successes that are occurring in the urology community.

Research in urology will involve urology surgeons, Ph.D. scientists, and non-urology surgeons.

The idea of “changing the culture” should not be viewed or presented as threatening, but rather as promoting scientific excellence.

#### **IV. DEVELOPMENT OF COMPETITIVE UROLOGY BASIC AND CLINICAL RESEARCH ENDEAVORS (PROJECTS)**

*Arthur L. Burnett, M.D., Johns Hopkins Medical Institutions, Baltimore, MD*

*Hunter B. Wessells, M.D., University of Washington, Seattle, WA*

##### **A. Focus Group Goals**

Dr. Burnett explained that the goal of the Projects Breakout Group was to explore possible ways for urologists and non-urologist basic scientists to collaborate. The Group was tasked with considering three key questions: (1) How important is it to do multidisciplinary research in urology? (2) What mechanisms facilitate multidisciplinary research endeavors? (3) Can mutual interests in the research outcome be met?

The Breakout Group would be discussing the importance of collaboration, including: whether collaboration would advance research and be conducted efficiently, specific techniques or resources that could be accessed, available funding, the ethos and availability of potential collaborators, and the compatibility of professional and scientific interests. Scientific collaboration can be particularly fruitful with the inclusion of complementary resources, insights, and talents, as well as cross-disciplinary expertise and vision. Additionally, there is no need to duplicate infrastructure. However, there can be issues of “turf” and primacy.

Dr. Burnett identified three ingredients needed for a successful collaboration: (1) institutional culture (Do clinicians and basic scientists interact? Do clinicians promote inquiry and discovery? Do basic scientists value translational research?); (2) departmental structure (Is a research effort supported? Are research grants and training grants sought? Are Ph.D. programs accessible to urology departments?); and (3) individual composition (Are all individuals committed to the effort? Will they make sacrifices? Can they give the necessary time and effort?).

##### ***Plenary Discussion***

Participants discussed how to make the best use of funding dollars. Comments were that future investigators will need different skills and therefore may require a new training path. Ph.D. students, for example, can be reached via a more physiological approach. It likely will be necessary to “push the envelope” to reach out in challenging and competitive areas; it was asked whether NIH could support innovative work.

## **B. Identification of Problems and Potential Approaches: Development of Competitive Urology Basic and Clinical Research Endeavors**

The “Projects” Breakout Group was given a list of questions to address during the breakout session, with a goal of developing recommendations for future research. Discussion of the questions is presented in the first sections of this breakout summary; following sections summarize recommendations for future urology research and provide points of discussion on other areas of concern.

1. *How do we overcome scientific and institutional barriers to basic and clinical urology research (i.e., symptom-based diseases, lack of tools needed to provide a technical and methodological foundation for future research efforts)?*

Scientific barriers to urology research are considerable, mainly because urologic diseases such as IC are symptom based. This is the current state of the science in urology. Urologic diseases generally are painful to the patient; useful biomarkers for these conditions have not been elucidated fully. A significant challenge is the multi-organ symptomology seen in many urologic diseases. IC, for example, presents as many diseases—neuralgia, digestive, and urologic. In addition, the study of urologic diseases includes not only the study of urology, but gastrointestinal, pain, and other common disorders. A strategy to address this issue could be to allow urologic problems to be studied from the focus of the gastrointestinal system, but in a multidisciplinary manner that includes urologic researchers involved in conducting clinical research, basic research, and technology researchers (e.g., imaging).

2. *How do we promote exploration of critical clinical questions within the basic science community and the translation of important basic science findings in clinical research?*

Translational research always should be the goal of clinical and basic research. Currently, very little funding is available for translating research findings to the clinic. This also is an area that could benefit from a “team science” multidisciplinary approach. A suggestion might be to support centers of research with a focus on symptoms of urologic diseases. Translational researchers could be involved at the earliest planning stages of this type of project.

3. *Is building the field best done through “growing out” (i.e., working to evolve from the existing nucleus and incorporate outside involvements as it proceeds) or from “growing in” (i.e., reconstructing the research enterprise through increasing outside influence from existing related disciplines)?*

There is no easy answer to this question for urologic research. Urology is being left behind compared to other medical sciences. It may be that the focus has been too limited in the past. In order to develop a multidisciplinary approach to urologic diseases, research should be broad, but focused. An example of a research topic that could benefit from a multidisciplinary approach is kidney stone research. An effort could be made to step across institutional research disciplines to create multidisciplinary studies that involve multiple departments. There are examples where this has been tried; it may be beneficial to develop examples that have worked to show that this

approach is viable. The NIH Roadmap initiative also may be a vehicle for developing cross-institute research.

4. *How do we create a cohesive structure for investigator-initiated projects that also create a urology community, promote multidisciplinary research, involve effective M.D./Ph.D. collaborations, and include a training component?*

In most scientific research disciplines, there is a competition for patients for clinical studies. Urology research has not been as successful as some other disciplines in recruiting these patients. The discipline would benefit from encouraging young investigators to become research-focused in urological sciences. It will be difficult, however, to identify these young investigators and provide them with adequate incentive to enter the field of urologic research.

A challenge in developing multidisciplinary urologic research has been the lack of information available to identify potential partners within the scientific community. A clearinghouse or database is needed that interested urologic researchers can consult to find researchers interested in specific topics or available resources that might be used by outside researchers.

Another challenge is the lack of institutional support within the study sections at NIH. Only a few study sections focus on urologic conditions; in contrast, kidney diseases have hundreds of study sections. There are many reasons for this disparity, but it is thought that a lack of data in urologic sciences makes it difficult for study sections to assess projects when the data are not available. This challenge also may impact the number of individuals who want to conduct urologic research. It is difficult to attract either M.D.s or Ph.D.s to research when there is little support within scientific institutions.

A training component is vital to increasing the number of researchers in urologic sciences. At this time, there is a lack of leadership and a “culture” that inhibits the study of urology. A strong mentoring system would encourage young investigators to pursue research in urology.

5. *For a few specific areas (perhaps benign prostatic hyperplasia (BPH), CP, IC):*
  - a. *What is NIDDK’s goal in this area?*
  - b. *What is needed to improve public health in the areas of prevention and treatment of urologic disease?*
  - c. *What are the most critical gaps in information?*
  - d. *What compelling public questions beyond what KUH is doing now are important and should be addressed?*
  - e. *What should be studied after current studies end?*
  - f. *Are tools needed?*
  - g. *What is the next clinical/translational study?*
  - h. *Are we ready to conduct such a study now, or are pieces missing (inclusion criteria, feasibility, etc.)?*
  - i. *Are there competing efforts by industry or others?*



### *Overall*

- *What are the first steps (e.g., is there a priority for efforts toward building people, places, projects, or tools)?*
- *Who will be responsible for initiating and enacting the various steps in this process?*

First steps include forging relationships between chairs of urology departments and research center directors. This would create an avenue to begin to address obstacles that have kept interactions within institutions from having a positive impact on urologic research. NIH could play a role in forging these relationships by issuing grants that require multidisciplinary and inter-institutional research. These grants could be issued for both basic and clinical research, or a mix of each, with training included as a significant part of the expectations.

To help define an approach to multidisciplinary research, NIH also could develop RFPs that address multidisciplinary research. An example would be an RFP on female incontinence. This is a good area to promote multidisciplinary research because exciting new research is occurring in the use of stem cells to make new urinary sphincters. This type of project would have a mix of basic and clinical sciences. The same can be applied to the study of IC and kidney stones.

### ***Summary of the Discussion***

The “Projects” Breakout Group summarized its discussions and made recommendations for further discussions at the next day’s breakout session. The breakout summary was characterized by discussions on (1) main themes, and (2) who can effect change. Main themes included: creating multidisciplinary research teams focused on general areas; communication and collaboration; identifying future clinical researchers early on and getting them into laboratories, including a focus on translational research early in the project; linking investigators; bringing new students into the field and providing ongoing training; and developing projects at institutions to integrate centers. Effecting change will depend on cooperation among each of the interested parties in urology research, including NIDDK, AUA, academic centers, and others.

### ***Plenary Discussion***

Dr. Star said that the O’Brien Centers will remain at the current number and at approximately the same budget. NIDDK must make difficult funding decisions with respect to centers, U01s, and R01s.

### **C. Developing a Short- and Long-Term Course of Action: Fostering Interactions/ Interdisciplinary Projects**

There is a lack of interdisciplinary understanding in the field of urology. Organ-related illnesses have clear pathophysiologies (e.g., congestive heart failure or kidney stone disease) and are easier to diagnose than urological diseases (e.g., painful bladder syndrome), which are symptom-based and require more interdisciplinary projects for diagnosis.

NIDDK is in a unique position to foster interdisciplinary projects because of the multi-disciplinary nature of the Institute (e.g., research on kidney stones, gastrointestinal issues, and

urology all are housed in the same location). The Institute has placed little emphasis on researching sexual dysfunctions, however, making it more difficult for investigators to make inroads in this area.

NIDDK could partner with other NIH Institutes to foster multidisciplinary symptom-driven disease research and to promote the concept of interdisciplinary centers for these diseases. NIH's Specialized Centers of Interdisciplinary Research (SCOR) program does this (see The Role of NIH, below).

### ***The Role of NIH***

NIH should state clearly that urological illnesses are symptom-driven and should propose specific projects to address this area. NIH could sponsor research to generate needed data, and other governmental agencies (e.g., the Agency for Healthcare Research and Quality, AHRQ) can help address the paucity of outcome measures in urology.

Research could be promoted to update the UDA-2 to identify or define further diseases needing treatment. The “impact factor” also must be assessed—spending a lot of money does not automatically mean that the project will have an impact.

Training in NIH should involve structured grounds that include urological investigators alongside basic science investigators.

The SCOR program requires strong interdisciplinary cooperation that involves both basic scientists and clinical researchers. The RFA for this program might be adaptable to urology. The SCOR model and the O'Brien Centers model use similar funding mechanisms. The SCOR program, however, provides more opportunities for transdisciplinary endeavors because it involves collaborations with several institutes and with both basic and clinical research sites. There is a concern that the O'Brien Centers only reward people who “already are in the club.” What about funding good scientists or funding scientists who conduct urology projects?

### ***Outcome Studies***

Outcome studies related to current urological practice are useful. The Center for Medicare and Medicaid Services (CMS) could conduct these studies. CMS could help elucidate areas that can be improved in NIH, as well as identify important problems.

Outcome studies will need to be translated into policy. These studies could help focus funding choices and other strategic decisions.

The ABU should consider developing an internal database. The resource would provide more micro-level data; NIH data tend to be at the macro level.

### ***AUA***

AUA can help promote the field of urology, such as via the American Foundation for Urologic Disease (AFUD) scholarships. AUA also can help set standards for research and reporting. For

example, AUA could define the qualifying limits for a particular study to be accepted for publication in a certain journal or for investigators to be invited to present at an AUA Annual Meeting. By raising the level of the research and having applicants succeed, the investigators might try harder to obtain NIH funding.

AUA also can promote the field by holding formal interdisciplinary sessions and sponsored lectures that bring in researchers from outside of the field to discuss matters of urological interest.

Another channel for raising interest in urology is to make certain projects “sexy” in a given year. For example, symptom-based diseases could be targeted for funding and advocacy.

It was suggested that the basic sciences component of the AUA meeting be broadened to increase the representation of fundamental research in urology. As an example, the experimental biology section usually accepts abstracts from a range of disciplines. Broadening the scope can entail having larger poster sessions. Presentations on basic science and clinical research can be interspersed to give a balance of coverage. Also progressive could be scheduling the Young Scientist Presentations during the regular programs rather than just during breakfast sessions.

AUA needs to be open to funding investigators other than young urologists. For example, AFUD scholarships currently do not support Ph.D. investigators. Also, AUA funding should not be discipline-restricted.

### ***Training***

Building the field will require capturing interest early in residency programs. If clinical training comes too late in a program, candidates might veer off in a different direction and no longer be easily engaged in urology. On the other hand, once an M.D./Ph.D. candidate enters the clinical realm, it can be difficult to return to the laboratory for basic science training. The AUA could support urology-focused spots or fellowships for M.D./Ph.D.s. This would promote urology as an option for those who are unsure of what area to pursue for their Ph.D. degree. Improving salaries for people also will help to make this decision more palatable.

Residency programs should maintain flexibility to allow for the possibility of pursuing clinical and/or academic studies. For example, those who are interested in specializing in basic science research often are so busy receiving clinical training that the possibility of research becomes an afterthought. The type of training venue influences career choice. Most academic centers, for example, focus on research training first and clinical training second. Moreover, department chairs tend to view the basic sciences as more important. Urologists should be encouraged to conduct basic science investigations in their field so that they can understand the relevance of their work.

Ph.D. staff can help an institution build expertise in basic science research. This would help doctors-in-training avoid having to develop the infrastructure for their own research. All residents should have some core level of exposure to the basic sciences, however, because any research initiative requires a central group of investigators to move projects forward.

In certain institutions, M.D./Ph.D.s are given faculty positions that permit them to apply for grants. For example, acting instructors or faculty members can apply for K-awards from NIH. Having a Ph.D. also can permit the hiring of a technician, which can help to further improve the basic science component in a department or institution.

NIH T32 grants (Institutional Training Grants) are awarded to M.D. residents mainly in their training year. NIDDK could broaden the role of T32s in urology training programs. For example, these grants could be advertised better. In the past, AUA has sponsored seminars or workshops to disseminate information on grant types.

Most departments at UCLA participate in the Specialty Training and Advanced Research (STAR) program. The program is an enriching experience and results in superbly trained doctors.

Projects, departments, and other entities within academic settings need to determine whether they should target certain areas or try to cover everything. For example, if a department already has three investigators working on kidney stone disease, it might prove beneficial to recruit new people in other areas to diversify the team. Having a few colleagues in a given area also has the benefits of allowing researchers to discuss ideas with each other and having relief staff available to trade off on shifts.

It is recommended that program directors examine their curricula. People who have a research interest can be encouraged to undertake more research during their training.

One concern is that redesigning a department to accommodate changes is a competitive process—if grants are not renewed in 4 to 5 years, there are dire consequences.

### ***Recruitment***

There is a need to recruit researchers from outside the urology field. It was agreed that department chairs play a significant role in this function. The chairs need to be receptive to the idea of expanding and diversifying their departments. A meeting could be held for the urology chairs to encourage open-mindedness toward this idea.

Funding is central to the success of attracting personnel. A professor who takes on a graduate student must have the salary available to support that individual.

Recruitment also requires incentives. For example, fellowships could be offered to Ph.D.s. People also must be encouraged to volunteer for studies. For instance, a basic science researcher who develops something that is implementable clinically will want to move it from the bench to the bedside and will need test subjects.

### *Crosstalk between Institutions/Communication*

It can be difficult to get M.D. and Ph.D.s from two institutions to interact. Artificial barriers are a problem. Interactions are needed to facilitate cross-appointments. As an example, cross-appointments in oncology at Johns Hopkins have promoted cross-disciplinary interaction. In some institutions, cross-appointments have an attached expectation that the cross-appointees hold teaching positions so that their knowledge is harnessed. Department chairs need to ensure that there is release time for their staff. It is a concern that staff cannot find time to hold meetings with researchers from other departments.

Certain types of centers have translational seminars at which investigators can learn about research in other areas. Similarly, some institutions have “mixed” centers (e.g., a diabetes or endocrinology center) through which researchers can apply for seed funds for pilot studies. Centers have more flexibility to move between basic science and clinical studies.

When a paper is published, it could be sent to a central place within an institution or an e-mail notice can be distributed informing everyone in the institution of the research. Likewise, when a key word comes up in a grant, an automatic electronic notification could be sent within the institution to inform others about ongoing projects.

Researchers could periodically have a mini-sabbatical during which they reach out to other investigators with whom they have not worked previously.

There is a missed opportunity with the Clinical Trials Network to obtain more information on basic science. Biomarker and ancillary studies should be communicated clearly, rather than being embedded in core clinical studies. Institutions and centers, however, are not necessarily the strongest locales to collect and process data. The key is to have the best groups do the collection; a recruitment center may not be as good at biopsies as a clinical center or other entity within an institution; this should be considered when planning projects.

### *Money/Time Issues*

Research proposals need to be evaluated to determine if the science would likely be considered meritorious and from where supportive funds should be sourced.

Departments should offer endowments to support their staff on cross-over time. It was suggested that staff occasionally be given a day off to focus on academic projects. In the meantime, the clinical projects still must be completed. Perhaps more “clinician clinicians” are needed (i.e., those focused entirely on clinical investigations). In this case, the “time off” arrangement must be implemented in such a way that the full-time clinicians do not resent not getting a similar change in their schedules. Perhaps rewards could be offered for conducting cross-departmental projects. Interactions might be rewarded at the departmental or institutional level.

### ***Other Suggestions***

Statistics could be used to promote a better understanding of the *status quo* of the urology field (e.g., data on the number of residents entering the field). Trend analysis also can be used to better understand changes in the structure of meetings and participant turnout. For example, did particular changes to AUA meetings (e.g., increased funding) result in greater recruitment of nonmembers? Surveys can be conducted to gauge the effect of changes on parameters of the field (e.g., numbers of participants or students). Baseline data also are needed to provide information about the paths taken by urologists in their careers (i.e., where do the academic programs lead?)

More information also is needed on outcome results to know how urological diseases are treated in different patient populations in the country. Also important for those studying urology is to be able to address diseases that occur in the United States to identify important topics to be researched (e.g., AUA can advocate for and fund these areas). The field also should consider how quality of life is affected by diseases.

Workshops could be held on certain topics (e.g., hold a Society for Urology Chairpersons and Program Directors (SUCPD) meeting at the next AUA meeting). New initiatives that have an improved presence within a urology program also can help elevate the program. It was noted that how the field is projected determines outcomes. Interactions and partnerships with advocacy groups that give time and funds could be encouraged.

NIH R01 RFAs should include coverage of some basic science in addition to clinical research. In some cases, however, it might be suitable for an R01 RFA to focus just on one topic (e.g., an RFA just on the epithelium that does not address the nerves). In other cases, an R01 RFA could focus solely on interdisciplinary approaches (e.g., the relationship between psychiatric and medical illnesses). The U01 Research Grants from NIH are another funding mechanism.

### ***Main Themes***

Enhancing competitive urology research endeavors will need a short-term focus on departments and interactions and a long-term focus concentrating on funding and training. Main themes covered in this overview included special emphasis areas, training future researchers to promote interdisciplinary projects, and the interactions between clinicians and basic scientists.

Various channels were proposed through which to foster interactions. These possibilities include AUA's hosting interdisciplinary mini-symposia and NIH offering an NIH R13 mechanism for travel. Another idea is to reconfigure the AUA Annual Meeting to engage and recruit more outside disciplines, such as by cosponsoring sessions with basic science organizations (e.g., American Physiological Society, APS) and sponsoring state-of-the-art lectures by outside researchers.

It was suggested that NIDDK expand the role of T32 grants in urology training programs. Resident training ought to include flexibility between basic science and the M.P.H./clinical research track. Facilitating urology departments to apply for and retain T32 grants also would be

beneficial, as would providing a program via the AUA and NIH to educate program directors about training grants, graduate programs, and so on. Training also would involve the appropriate sourcing and allocation of funds, such as NIH funding for graduate-level training and AUA's funding of slots in M.D./Ph.D. or Ph.D. programs to concentrate in urological areas.

NIH's role in augmenting urology research could include the prioritization of problem areas in urology. For example, the UDA-2 could expand on and explore quality of life issues and treatment variation. Also critical is addressing the paucity of outcome measures in urology via such bodies as AUA, CMS, and AHRQ, in addition to NIH.

In focusing on research, NIH could emphasize symptom-based diseases. Options include focusing on Clinical Trial Networks to integrate basic and clinical researchers. Also a possibility is basing O'Brien Centers on the SCOR model, which can involve mandating interdisciplinary interactions and creating an institutional network.

"Organized Research" will help the realm of urology research by targeting symptom-driven diseases for AUAF fundraising, allocation of research funding, and coordination of patient advocacy groups. Other benefits include opening AUAF funding to outside urological researchers and playing a role in outcome studies.

The department chair has a critical role in the described areas of focus. In fostering interactions, the chair's priorities would involve securing funding to generate preliminary data, facilitating cross-appointments, permitting residents into other laboratories, providing incentives to attract outside Ph.D.s, and hosting seminars with prominent outside faculty. Regarding resident research training, the chair would aim to permit flexibility in curricula to accommodate different pathways (e.g., M.P.H., basic science, no research). Another channel is to enlist Ph.D.s in the development of curricula. To foster research, the chair will need vision and commitment, as well as strategic decision-making about research emphasis and focus. It also will be essential to have a critical faculty mass in specific areas of strength.

### ***Plenary Discussion***

There is a national organization of academic chairs that could be included as a stakeholder. It was suggested that the 2008 AUA meeting include a session for department chairs to discuss mechanisms and strategies to improve research.

## **V. CREATING AN ENVIRONMENT FOR UROLOGY RESEARCH AND TRAINING: INSTITUTIONAL SUPPORT (PLACES)**

*E. Darracott Vaughan, M.D., Cornell University, Ithaca, NY*

*Richard D. Williams, M.D., University of Iowa, Iowa City, IA*

### **A. Focus Group Goals**

Dr. Williams explained that the "Places" Breakout Group would define impediments to high-level basic and clinical research in urology today. This would include important scientific issues: What are the burning clinical questions? Are there trained investigators to answer them?

The clinical trial and translational funding mechanisms are sparse, and there is a low level of interest among basic scientists in applied or translational research. It also would address institutional-level concerns, such as: no registry of relevant funded investigators and projects, the current emphasis on clinical services and revenue, no clinical trials support unit, and minimal start-up funding mechanisms.

Several methods could be used to help basic scientists answer critical clinical questions and translate findings to the patient. These include defining clinical questions (UDA), developing funded clinical trials units, developing funding mechanisms that require and reward clinical trials for initial and continued funding (e.g., translation of new findings), and requiring funded institutions to provide infrastructure for trials and translational projects.

The best urology research needs to be built from within and involve other disciplines. In addition, more established research units can provide infrastructure for urology research.

It is important to determine how to develop collaborative M.D. and Ph.D. urology research teams. On the national level, this would require more involvement of Ph.D. scientists in AUA/AUAF, as well as increased interactions of M.D. researchers in SBUR and other organizations. Locally, collaboration would be abetted through equal partnership in departments and improved resident research.

Dr. Williams explained that the Breakout Group would identify necessary action items, including next and further steps, the measurement of progress, and responsible parties.

### ***Plenary Discussion***

The issue of indirect costs was discussed. Rates are negotiated at the NIH and university levels. A participant mentioned that he had heard that a “tax” might be added onto direct costs to help cover the cost of infrastructure. Another participant commented that the issue surrounding indirect costs distracts investigators from their research and papers.

Northwestern University and the University of Pittsburgh both use a unique system in which the institutions receive 90 percent of the indirect cost fees and give the grantees an appropriate portion of the money, provided that they show that 15 to 20 percent is invested back into research; this encourages an entrepreneurial atmosphere.

## **B. Identification of Problems and Potential Approaches**

The Institutional Support Breakout Group discussed the problems involved with institutional support in urology research. Dr. Vaughan presented these ideas to the Plenary Group at the end of Day 1.

Dr. Vaughan noted that, as changes are made in the basic sciences, it is important for clinical research centers to “look outside the box,” as innovation in funding benefits both institutions and researchers. Institutions also must continue to pursue flexibility in training programs to better support research.



Several institutions now use fund sharing, in which a portion of a department's indirect research funds are paid to the institution. Department chairs then provide investigators with approximately 27 percent of their research funding needs, which can be used toward post-doctoral requirements. Positive aspects of fund sharing include encouraging entrepreneurial efforts and well-planned funding mechanisms for research. Fund sharing also typically creates less demand for space because investigators must pay for office/research space from the funds provided to them. The biggest advantage for departments is that they can manage their own money.

Urologic clinical research centers of excellence may advance urologic research most effectively. Researchers and institutions currently making strides in urologic science must be supported, with the mandate that new researchers must be recruited and become fundable; urologic research, as opposed to the creation of departments of urology, should be the research goal.

### ***Residency Training***

Research workforce needs in academic urology and research focus tracts need to be defined. Developing more integrated degrees that encourage creativity will promote urology research. Integrated degree programs should be vertical and include fellowship and faculty development, while encouraging interdisciplinary collaboration. Vertical integration programs that are mutually supportive for researchers, provide camaraderie, and enhance interaction among investigators have a high success rate.

Currently, several M.D. and Ph.D. programs are structured on a continuum, though these degrees usually require a large program to support them because available resources from large departments usually are more robust than those generated from smaller departments. Managing laboratory rotations within urology departments can be difficult, however, because at least three residents are necessary each year to support a year of laboratory research within integrated degree programs, and many urology departments have only two residents per year. Some institutions guarantee laboratory time (e.g., 2 or 3 years) for investigators but require them to apply for outside funding.

The Resident Review Committee encourages innovative programs at research institutions to ensure diverse training. Since 2005, urology programs also have promoted and supported pioneering investigative programs at research institutions. A primary concern of many institutions is to reduce the amount of time investigators spend in residencies rather than "real" employment and to integrate interests with appropriate programs and institutions. Residents should be encouraged to have baseline or core curricula with laboratory time, which would be included as part of their fellowship requirement.

Historically, individuals who are associated with comprehensive cancer centers have greater access to interdisciplinary research and better access to research teams. Expanding the cancer center concept to include heart and lung centers, digestive disease centers, and other comprehensive centers is one option under consideration by urology investigators.

Issues concerning the academic enterprise and how it affects the field of urology must be addressed by institutions and departments. The number of academic urologists that should be trained annually, where the training should take place, and how to attract the best candidates to the field need to be determined. Creative and innovative solutions to these issues are needed to advance urology research. Providing faculty status to Ph.D. residents, which allows them to apply for grants, helps to ensure residents' satisfaction and fundability. Such measures also encourage inter-institutional opportunities for career development.

Forums can be held for presentations by junior researchers to encourage and support resident researchers; such forums should include discussions by leading academicians. Organized urology meetings also could provide a platform to increase recognition of residents' and junior faculty research.

### ***Faculty Development***

Formal mentoring programs at the institutional, regional, and/or national level help support young academics in urology research. One component of the mentoring process should be to ensure that new academics are well prepared and have the tools to be successful in their work. Such programs are instrumental in retaining researchers and increasing funding opportunities; the number of institutions that are implementing formal research training is increasing. Individuals involved in urology research could be funded as part of the CTSA program, which would enable institutions to use the CTSA infrastructure. Mentors can include funded scientists who, as an addendum to their grants, formally mentor a junior investigator; this arrangement is similar to the National Research Science Award grants, but would focus on individuals rather than on departments or institutions.

Because urology research involves more than basic science research, many institutions now require new faculty to have clinical research education or experience, particularly for clinical trial work. Opportunities should be available to junior researchers to obtain advanced degrees that lead to success in clinical research and trials, with research being defined in the broadest terms.

There is a need to advance urologic research, and diverse specialized paths—including Ph.D.s and M.D./Ph.D. degrees—can facilitate this research. An enabling and nurturing environment should be provided for Ph.D. researchers who are interested in working with urologic problems and in mentoring new urologic faculty. This environment should not only include time for research but also provide incentives for encouraging research activity.

### ***Institutional Environment***

Currently, there is no registry of relevant funded investigators and projects. Such a registry would encourage greater interdisciplinary and collaborative research and promote interaction between new investigators and outstanding academicians in the urology field. Although local registries would be valuable, regional and national registries would have the most impact on urology research efforts.

Institutional research support should include the following:

- Information technology to advance research effectively and efficiently
- IRB support for investigators
- Serum and tissue banks
- A master patient index
- Outcomes and procedures data banks
- Data protocol management

Clinical trial support is lacking at many funded institutions. Funding mechanisms are needed that require initial clinical trials and reward these trials with continued funding. Infrastructures also must be in place to support clinical trials and translational research projects. One option is for institutions to establish funded clinical trial units.

Funding also is sparse for established investigators. Research time and opportunities are jeopardized when urology departments require investigators to spend significant amounts of time performing clinical work for salary purposes. Collaboration with other disciplines may provide new ways of funding urology research for existing researchers. Funding opportunities from a variety of sources, including industry, should be considered as well as multidisciplinary projects. Urology research will advance most effectively if institutions find ways to promote urology research for new and established researchers.

### *Plenary Discussion*

The Breakout Group was encouraged to focus on funding issues in Day 2.

The number of researchers needed is not fixed. Urology covers very important human diseases, but it is not recruiting the numbers of people needed to advance research significantly.

It was pointed out that there is a cycle of funding; sometimes medical schools receive more, other times hospital systems are the major recipients. CMS and hospital accreditors should include the creation and maintenance of databases as accreditation criteria. NIDDK investigators possibly could tap into those databases for research needs. A participant raised potential information technology (IT) issues, noting that database structures might be created that are not compatible with other software or useful for research analyses.

### **C. Developing a Short- and Long-Term Course of Action**

Dr. Williams began the breakout session by pointing out the need to identify specific recommendations and action steps. Four specific goals were identified:

#### *Goal 1—Define research workforce needs in urology*

The discussion began with question to help clarify the meaning of this goal: Is the goal to improve urologic research or to increase the number of urologists conducting research? The group agreed that both were important. Thus, to define research workforce needs in urology it

would be necessary to: (1) identify the type of researchers needed (e.g., M.D.s, Ph.D.s, others?) and (2) define the specific basic and clinical research questions to be answered.

### ***Goal 2—Prepare competitive urologic investigators***

Institutions can strengthen and improve their training programs in a number of ways. One way would be to establish formal mentoring programs for trainees and faculty. Another would be to encourage and expand participation in formal clinical research training programs. The group noted the lack of departmental support for beginning investigators in many institutions. The group also discussed revising existing training paradigms to encourage the production of urologic investigators. It was noted that current training programs (residency, fellowships, etc.) lack a formal research training component and, thus, often produce M.D.s with little understanding of research.

### ***Goal 3—Expand interdisciplinary and collaborative investigation***

To support the expansion of interdisciplinary and collaborative investigation, institutions could build infrastructure to better support those who are interested in pursuing urology research. In addition, more funding is needed to support urologic research. The current lack of funding for basic urological research is a major barrier to expanding the research base. Issues such as prostate cancer and erectile dysfunction tend to garner media attention (and funding), whereas less glamorous issues such as urinary incontinence generally do not. Another way to support and encourage collaboration would be to create a registry of funded investigators and projects related to urology. Additionally, attracting more clinical and basic scientific investigators to the field could expand the research base and allow for more collaboration.

### ***Goal 4—Increase the funding base by identifying novel and unique funding flow models and sources***

The group discussed methods to increase funding support for urology research, including increasing the number of NIDDK research training grants available to urology researchers. Another means of funding research would be to identify fund-matching opportunities, focusing on industry, AUA, the institution, and NIDDK as potential funding sources. Additionally, a primer on funding research and research time could be offered to institutions looking to expand their urologic research base. In these sessions, institutions with successful research programs would share their experiences and best practices.

The organizations and institutions that are responsible for each of the four goals above were identified. These include: departments, institutions, the AUA, NIDDK, ABU, RRC, industry, and urologic societies.

Potential metrics for evaluation were identified, including (1) the number of awards received and the total dollar amount; and (2) other outcomes, such as improved drugs and treatments, better understanding of the mechanisms of benign urologic diseases, improved quality of life for patients, development of biomarkers for specific urologic disorders, and career accomplishments in research from M.D.- and Ph.D.-funded scholars.

The group also discussed additional barriers to urology research, such as a prevailing culture within many urology departments that discourages urologic research. A suggestion was made that urology might look to other medical departments, such as internal medicine or surgery, to learn innovative ways to encourage research within urology departments. For example, the department head of internal medicine departments often is personally responsible for the success or failure of each and every trainee in the department.

Another topic discussed at length was the lack of funding for many areas of urologic research. Foundations focus their efforts on specific, high-profile health issues, such as prostate cancer. Academic institutions determine where scarce funds will go, allocating funding to areas such as women's health (which encompasses some urologic issues), but often do not allocate money for more general urologic research. One participant suggested approaching industry for funding in areas of interest to industry, such as urinary incontinence.

A larger issue, at the heart of many of the issues above, is the fact that the general public still does not know what urology is. Discussion turned to how to go about informing the public about the field. Who should be responsible for educating the public? AUA? others?

### ***Plenary Discussion***

Dr. Star agreed with the Breakout Group's development of metrics, which went beyond numbers to reach the real impact.

A forum on how successful departments were developed would be useful. The Professional Society of Medicine has developed a course for department chairs. Dr. McConnell requested a copy of the society's information and program agenda.

The plenary group briefly discussed issues surrounding NIH grants, including competition with surgical responsibilities, the routing of grant monies, and taxation of funds.

## **VI. DEVELOPING A TECHNICAL/METHODOLOGICAL FOUNDATION FOR UROLOGY BASIC AND CLINICAL SCIENCE (TOOLS)**

*Robert H. Getzenberg, M.D., The Johns Hopkins University School of Medicine, Baltimore, MD*  
*John D. McConnell, M.D., University of Texas Southwestern Medical Center, Dallas, TX*

### **A. Focus Group Goals**

Dr. Getzenberg explained that the "Tools" Breakout Group would discuss the scientific barriers to basic and clinical urology research, and the tools needed to provide a technical and methodological foundation for future research efforts. An important consideration will be how to develop and apply these tools, particularly to the field of urology.

Examples of current technologies include: microarrays, single-nucleotide polymorphisms (SNPs), epigenetic patterns, proteomics, focused approaches (such as looking at the kinome and

metabolome), and nanotechnology. Diagnostic and prognostic approaches for assessing disease states are important, as well as therapeutic monitoring strategies. Shared resources for tissue, serum, and urine banks also need to be considered, along with appropriate cell and animal models.

Dr. Getzenberg summarized the principal questions that the Breakout Group would discuss:

- What technologies/methods should be applied first?
- What are the most important questions that can be answered with these technologies?
- What types of expertise or training are required to move these forward?
- Who will be responsible for what phases of the process?

## **B. Identification of Problems and Potential Approaches**

The group discussed the assigned topic and developed the following list of solutions and barriers, along with a new Centers concept:

### ***Barriers to Basic Research***

- Inadequate understanding of normal development, pathways, and other aspects of the basic biologic processes in the GU tract
- Knockout mice developed in nonurological research laboratories are not cross-referenced for GU importance and are not adequately phenotyped.
- Inadequate input and leadership from urologists regarding applicability and significance in basic and translational research studies
- For urology researchers, becoming “independent” is increasingly challenging—independence often does not occur until the researchers are well into their 40s. This significantly limits the attractiveness of an academic career for both Ph.D. and M.D. investigators and often produces burnout.
- Too many boundaries exist between disease processes—e.g., a grant that proposes a link between infectious disease and IC may not even be reviewed.
- Lack of involvement of urologic investigators in graduate student and medical student education.
- Lack of standard urothelial cell systems, GU stem cells, terminally differentiated umbrella cells, stratified urothelium, GU smooth muscle cells, and defined growth conditions
- Lack of high-quality, well-annotated human specimens for discovery (tissue, urine, serum)

### ***Basic Research Solutions***

- Recruit nonsurgical urologists or physicians from other areas with urologic expertise (as has been done with GU medical oncology).
- Develop an infrastructure to support young investigators (e.g., address helping with IRBs, laboratory management).
- Take advantage of investments and knowledge in cancer (for example inflammation) and apply them to “benign” research; promote cross-fertilization.

- Educate basic scientists regarding the importance (and potential excitement) of research in urologic disease.
- Emphasize physiology.
- Develop better modeling systems, including canine models.
- Develop more reference samples—consider issuing an RFA for “normal” prostate and other tissues; should be renewable and “rolling.”
- Standardize urothelial cell systems, GU stem cells, terminally differentiated umbrellas cells, stratified urothelium, GU smooth muscle cells, and growth conditions.
- Learn about tissue acquisition from the National Cancer Institute (NCI) (e.g., breast).
- Conduct a workshop on the acquisition and storage of tissue, serum, and urine.
- Increase funding for dedicated sample acquisition.
- Develop a comprehensive list of knockout mice that may have GU importance.

### ***Barriers to Clinical Research***

- A standard definition of the disease is often lacking; also, some existing definitions limit creative thinking (e.g., infectious etiologies that may trigger IC).
- Over-reliance on pathologic definitions
- Inadequate phenotyping of symptomatic disease (complete and uniform)
- Lack of standardization in sample collection and storage
- Translational studies are not begun early in clinical trials (waiting to the end of the trial is problematic).
- Inadequate consideration is given to the basic science portions of clinical trials during trial design, including consideration for consent, sample acquisition, and storage.

### ***Clinical Research Solutions***

- Include adequate discussion of the basic science portions of clinical trials during trial design. This discussion should address such items as consent, sample acquisition, and storage.
- “Embed” basic science studies into clinical trials by changing the way clinical trial RFAs are released: use a two-pronged (clinical and basic) approach, with separate review and a joint steering committee structure.
- Encourage the development of translational-oriented pathology and pathologists.
- Address sample annotation and quality of storage.
- Develop an RFA to address standardizing urine collection and storage.
- At larger centers, consider Core Funding mechanisms for tissue acquisition and storage; also consider instituting a collaborative tissue network (e.g., NCI’s Cooperative Human Tissue Network, CHTN).

### ***Centers Concept***

- May attract investigators from other areas.
- O’Brien Centers are too small and not structured. More comprehensive centers are needed that are not so disease focused; highlight basic, translational, and clinical (investigator-initiated) research.

- The centers may develop new tools, but it probably is best to distribute the tools through collaboration rather than as a “service.”

### ***Additional Comments***

The following points were raised in discussion:

- The dearth of basic knowledge about urologic disease is a serious problem. Other fields are better developed.
- Urologic disease research needs to be driven by urologists or it will not happen at a sustainable level. Separate tracks are needed for clinicians and scientists. It is important to involve M.D.s with clinical knowledge.
- AUA is aware of these issues. The field is changing, and leadership must prepare for the changes.
- The databases that currently are available for understanding the outcomes of interventions are woefully inadequate.
- Basic scientists need to be educated about urologic models; the scientific community needs to be better educated about the value of urologic models.
- Clinical definitions are mandatory for clinical trials but are not helpful in discovery; power and information are lost.
- Pilot mechanisms can be added to clinical trials to enhance the basic science component of a trial.
- Input from pathologists is needed early in the design process for clinical trials.
- A group process should be used in deciding what hypotheses to pursue in trials.
- Different institutions could conduct the clinical and basic science portions of a single trial.
- The urology community is small enough to allow customization in centers.

### ***Plenary Discussion***

There are model systems for RFAs that could be followed, such as the RFA on the epithelial cell.

### **C. Developing a Short- and Long-Term Course of Action**

The group refined its discussion of the previous day’s topics, as follows:

#### ***Barriers to Basic Science and How They Might Be Addressed***

Barriers to basic science include a lack of understanding of many aspects of the normal biology of the GU tract, including development, regulatory pathways, inflammatory response, changes with aging, and stem cells and differentiation. Another barrier is inadequate statistical design and analysis. The group recommended addressing these barriers by emphasizing physiology, especially in mouse knockout models. In addition, urology should take advantage of investments and knowledge in cancer and inflammation and apply them to research in benign disease. In addition, incentives should be implemented to promote cross-fertilization among fields and disciplines.



People-related barriers include the lack of input and leadership from urologists regarding the applicability and significance of basic and translational research studies. In addition, for urology researchers, becoming “independent” is increasingly challenging—independence often does not occur until the researchers are well into their 40s. This significantly limits the attractiveness of an academic career for both Ph.D. and M.D. investigators and often produces burnout. Recommendations for addressing these barriers included recruiting nonsurgical urologists or physicians from other areas with urologic expertise, as has been done in GU medical oncology. In addition, an infrastructure should be developed to support young investigators, especially in areas such as working with IRBs and laboratory management.

Education can be a barrier because of the lack of involvement of urologic investigators in graduate student and medical student education. The group recommended educating basic scientists about the importance (and potential excitement) of research in urologic disease.

Models and reagents are barriers because of the lack of standard urothelial cell systems, GU stem cells, terminally differentiated umbrella cells, stratified urothelium, GU smooth muscle cells, and defined growth conditions. The lack of high-quality, well-annotated human specimens for discovery (tissue, urine, serum) represents another problem area. Animal models present a problem because knockout mice developed in nonurological research laboratories are not cross-referenced for GU importance and are not adequately phenotyped. In addition, most appropriate models have not been developed to address many questions. The lack of standard characterization of animal models (methodology) is another barrier to basic science. To address these items, the group recommended implementing a workshop to design a central, searchable, web-based reference catalog for relevant GU tissue and protein arrays, samples, and animal models (similar to FLYBase). Questions to be addressed regarding this database include whether to allow industry access. Better modeling systems, including canine models, should be developed. More reference samples are needed, and consideration should be given to an RFA for “normal” prostate and other tissues; these samples should be renewable and “rolling.” Also, urothelial cell systems, GU stem cells, terminally differentiated umbrella cells, stratified urothelium, GU smooth muscle cells, epithelial-stromal models, and growth conditions should be standardized. In addition, the field should attempt to build on NCI’s experience with tissue acquisition (e.g., breast). Other recommendations included promoting a workshop on tissue, serum, and urine acquisition and storage; increasing funding for dedicated sample acquisition; and developing a comprehensive list of knockout mice that may be useful in GU studies.

### ***Barriers to Clinical and Translational Research and How They Might Be Addressed***

Disease definitions present a problem in this area because they often are lacking and may include inadequate (incomplete and not uniform) phenotyping of symptomatic disease. Disease definitions also can limit creative thinking (e.g., infectious etiologies that may trigger IC), and can influence grant reviews. Over-reliance on pathologic definitions is another problem. Disease definitions also should be considered “works in progress,” to be redefined as the science changes. Mechanisms for ensuring that such changes are widely disseminated also are needed. Multidisciplinary consensus conferences on disease definitions for BPH and lower urinary tract systems (LUTS), IC, and prostatitis would address these concerns. NIDDK is in the process of developing such a meeting; group members were urged to send suggestions about the meeting to

Chris Mullins. The definitions developed during these conferences, however, should not be used to restrict hypothesis-driven translational research. Recruiting pathologists and radiologists who are translation oriented, building interdisciplinary teams, and creating incentives for pathologists and radiologists to ask GU questions and collaborate on studies are other means of addressing these issues. In addition, NIDDK should encourage or insist on the inclusion of pathology and radiology co-investigators on relevant grants.

The lack of standardization of sample collection and storage presents another problem in this area, along with the absence of comprehensive databases. Addressing sample annotation and quality of storage would be helpful. In addition, NIH should consider issuing an RFA to encourage standardization of urine collection and storage procedures. Core funding mechanisms for tissue acquisition and storage, similar to the CHTN, also should be considered at larger centers.

Clinical trials design can present problems because translational studies often do not begin early in a clinical trial, and conducting translational studies at the end of a trial can be problematic. In addition, the basic science portions of a trial often do not receive adequate consideration in the trial design phase. Items that should be considered “up front” include consent, and sample acquisition and storage. In addition, efforts should be made to engage the basic science community (e.g., SBUR) in NIDDK’s pre-RFA planning. Basic science studies could be “embedded” into clinical trials by changing the way in which clinical trials RFAs are released. A two-pronged approach that includes both clinical and basic science, separate reviews, and a joint steering committee structure should be considered. In addition, adequate statistical design and analysis should be encouraged.

The group also recommended developing or adapting new advanced imaging tools (e.g., positron emission tomography (PET) and magnetic resonance imaging (MRI)) for human and mouse models. NIDDK should consider issuing an RFA concerning the development of advanced imaging techniques in urology that encompasses both mouse models and human translation.

### ***Expansion of the Centers Program***

The group also urged NIDDK to expand the Centers program to attract investigators from other disciplines. The O’Brien Centers are too small and not structured to address the gaps noted above. More comprehensive Centers are needed that are not so disease focused to encourage the leveraging of quality science within and between institutions. These Centers do not have to be awarded solely to urology departments. The Centers should be based on the Comprehensive Cancer Core grant model and encompass basic, translational, and clinical (investigator-initiated) research, with cores. The Centers may develop new tools, but it probably is best to distribute the tools through collaboration rather than as a “service.”

### ***Summary of Recommendations by the Tools Breakout Group***

The group summarized its recommendations as follows:

**Recommendations for Organized Urology (e.g., AUA, SBUR).** (1) Organized urology groups should cofund some NIDDK initiatives, such as planning workshops and resource databases. (2) These groups also should develop and implement strategies to engage more basic scientists in their annual meetings. (3) The groups should develop satellite or “guest society” meetings on GU translational research at the Federation of American Societies for Experimental Biology (FASEB) and similar meetings or should enhance the SBUR meeting.

**Recommendations for Urology Department and Division Chairs and Local Institutions.**

(1) Attract people into collaborative models, such as nonsurgical urologists or physicians from other areas with urologic expertise—as has been done with GU medical oncology. (2) Co-invest in multidisciplinary recruitment (i.e., urology departments and nonurology departments). (3) Develop an infrastructure to support young investigators, especially in areas such as working with IRBs and laboratory management. (4) Educate basic scientists regarding the importance and potential excitement of research in urologic disease.

**Recommendations for NIDDK.** (1) Include representatives of basic science, imaging, and pathology in NIDDK’s pre-RFA planning workshops. (2) Release dual RFAs for clinical trials and relevant basic and translational science to be conducted on specimens obtained in the trial. These aspects should be reviewed separately. Steering groups should be coordinated and have ongoing external review. Funding for basic science should be integral to all trials (as it is in SCORs and Special Programs of Research Excellence, SPOREs). (3) Develop, through a workshop consensus approach, standards for sample acquisition, storage, and annotation. (4) Develop Disease Definition Consensus Conferences that include basic scientists and epidemiologic experts from outside the disease-specific community. (5) Conduct a workshop to design a central, searchable, web-based reference catalog for relevant GU tissue and protein arrays, cell lines, metabolomics, samples, animal models, and knockouts, similar to FLYBase. (6) Develop and adapt new advanced imaging tools (e.g., PET, MRI) for human and mouse models.

**Recommendations Regarding Transforming the O’Brien Center Model to Resemble SPOREs.** (1) The SPORE grant model includes basic, translational, and clinical (investigator-initiated) research, pilot programs, and career development. The O’Brien Centers should be based on a similar model. (2) A major goal of these Centers should be to bring in new investigators. (3) Interaction between Centers should be required. (4) A single GU disease focus should not be required; the emphasis should be on fostering the best science.

**Recommendations Regarding Metrics.** (1) Increase the number and diversity of interests of new urology investigators. (2) Increase interactions between groups focused on urologic diseases. (3) Develop a database and website with available resources. (4) Integrate basic science into the design of new NIDDK clinical trials.

***Plenary Discussion***

The Plenary Group briefly discussed the need for joint meetings that would promote cross-fertilization and integrate disciplines better.

## VII. Summary Comments and Action Plan

Dr. Star asked participants to summarize an idea that they felt was valuable to take away from the workshop. Participants thanked Dr. Star and NIDDK for organizing the workshop and offered the following comments:

- Recurring themes from the workshop included the productive nature of talking between departments and the need to improve the Computer Retrieval of Information on Scientific Projects (CRISP).
- Basic science should be embedded early into the decision-making components of clinical trials; this would allow cross fertilization.
- Similar types of activities (e.g., genetics and imaging) are occurring across organizations.
- Participants would like to receive the workshop minutes. (Dr. Star said that the summary would be ready in 3 to 4 weeks and that it would be disseminated to the whole group.)
- A significant amount of work is being done by many groups.
- The meeting might have been too negative about the urology research currently being conducted. It is important to create an environment in which people are protected and have time for research.
- The AUA meeting is likely to be receptive to this workshop's ideas.
- It was a useful meeting. Training in urology residency and fellowship needs to be integrated, but it is not clear who should assume this responsibility.
- What is occurring in the urology field is parallel with many other fields, such as anesthesia.
- Participation on review panels is a virtue of serving the community.
- We should focus on inputs that improve where we are now and how we can do the best science.
- The AUAF's Research Task Force work is important, and increased interactions should occur with NIH and NIDDK; this meeting is helping to jumpstart that. There is a value in having non-urologists share their experiences at urology fora, so that we can learn from best practices. This workshop highlighted the need for leadership in urology.
- NIDDK is committed to addressing issues and discussing with the community the next steps for NIDDK.
- The process perspective was educational.
- We must recruit people early.
- Many common themes resonated throughout the workshop; the issues that face urology do not concern funding only. It is time for a new education model, and it is important to communicate with and outside the urology community.
- Junior faculty should be helped; changes for trainees could include short-track training.
- It is important to think about how to move clinical research forward rapidly to improve human health.
- Research is fundamental. Increased flexibility is needed and should be formalized in earlier stages. Support is needed on multiple levels. To move urology forward, we should create better interactions. Partnerships are needed, and infrastructure does make a difference. We should look at successful models in more depth.

- There is a need for an organized, cohesive urology. Clinical research and outcomes should receive attention. We must continue to stress the importance of people and identify their strengths and flexibility in training.
- The urology training grants study sections are not doing well. We should recruit basic scientists into urology departments. It is noteworthy that basic scientists generate 50 percent of their salaries, but urology researchers generate 100 percent of theirs. We can identify 15 to 20 institutions that provide good training, but all urology departments should pay attention to research.
- We need effective leadership to enact concrete recommendations. Effective leadership is local and sits on the shoulders of department chairs.
- I learned about working in urology departments. You need to get fabulous trainees into urology.
- To promote urology research, we should grab the best and brightest students early and invest in them. We need to collaborate with basic science in other departments.
- A participant commented on the complexity of the landscape and the need to reach and help assistant professors.
- It is important to advance the best science.
- I was impressed with the workshop interactions from everyone, including non-urologists. This meeting could be a watershed for urology.
- It remains all about the money and the challenges of funding and time for research. Bright people are entering the field.
- The timing of the meeting was good.
- NIDDK facilitates research. We should move to more analytical function and bring more people to participate. In addition, adding more sample sets and data sets to NIDDK's repository could serve as an incentive for young researchers.

### ***Final Comments***

*Drs. John McConnell, Anthony Schaffer, and Robert Star*

Dr. McConnell expressed his appreciation for the participation of non-urology colleagues. The most important thing that can be influenced is the environment surrounding the young people. The shortening of training is a key idea. He suggested that, within the next 6 months, AUA and RRC should create a subgroup on the topic that invites basic science input. The issue of integrating training into urological residency and fellowships also should be discussed and recommendations made by that group.

The responsibility for mentoring junior faculty should be in the hands of department chairs. NIDDK can provide better tools to department chairs to support the transition timeframe to independent grant funding.

The transformation of the O'Brien Centers program is important. The field of prostate cancer research has been transformed, and the same mechanism can be used to transform urologic research. With an academic medical center environment that embeds basic science into translational research programs at the beginning, the people engaged in such kinds of studies will attract young people.

Dr. Schaffer said that he was enthused about the opportunity to activate some of the workshop's ideas and hoped that attendees would participate in the Research Council's effort to enact them. We are trying to be more inclusive and will involve as many Ph.D. and M.D. scientists as possible. New Task Forces will need members.

Dr. Star thanked everyone for attending the workshop. He learned from the group that the state of the science and the state of the health of the field are better than NIDDK macroeconomic numbers were showing.

To improve the field, however, concerted, collaborative efforts are needed to attract and train investigators in a well-formed research environment and provide new tools and research structures to make tremendous progress in urology science. The suggestions of ways to change assorted institutional training and career grants will be helpful, and the amount of flexibility that already is built into the system can assist with achieving some of the solutions (e.g., an extra research year and the timing of training). NIDDK will work with AUA to bring a research-development kind of grant-writing course to the AUA annual meeting, as well as continue to work on other national programs for career development.

NIDDK can help with several of the database recommendations. In addition, a planning grant for multidisciplinary studies to help researchers find each other in the institutions and co-develop projects also could be worked on, perhaps beginning with an announcement for multidisciplinary research.

In terms of institutions, it is clear that, similar to internal medicine departments, urology departments were built up one at a time as a cottage-kind of industry, without a structure available to train people to become effective department chairs. Dr. Star also noted the strong sentiment that was expressed about restructuring the O'Brien Centers program.

Many good ideas were shared about tools, including new imaging tools, pathology tools, and a workshop for sample collection. Another useful idea was to solicit basic science input into a clinical trial design while the protocol is being written.

Dr. Star said that the purpose of the workshop was to find solutions to current issues facing the field, and that many solutions were presented. NIDDK may organize small meetings about specific topics if needed. It is expected that a follow-on workshop will occur within 9 to 12 months to ensure that progress is being made in the right direction and that there are no gaps in addressing the problems.