National Institute of Diabetes and Digestive and Kidney Diseases

Individualizing Urinary Incontinence Treatment—Evolving Research Questions to Research Plans

Pre-Meeting Workshop: Establishing a Career in Benign Urologic Conditions

Natcher Conference Center, Building 45
National Institutes of Health
Bethesda, MD 20894
February 1, 2018

Workshop Report

Welcome and Workshop Objectives

Tamara Bavendam, M.D., M.S., Senior Advisor, Women's Urologic Health, Division of Kidney, Urologic, and Hematologic Diseases (KUH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Dr. Tamara Bavendam welcomed attendees to the pre-meeting workshop. She remarked that participant feedback from the March 30, 2017 NIDDK Workshop on Individualizing Treatment for Urinary Incontinence (UI) suggested that participants desired a workshop on careers in benign urologic conditions research. In response, this workshop was developed to provide the opportunity to learn about institutional resources, ways to overcome the challenges of balancing research with clinical responsibilities, and sources of funding. The objective is to provide, in a small setting, a structure for attendees to meet and interact with people who can stimulate and support their research efforts. Mentorship breakfasts, elevator pitches, poster sessions, and group dinners had been arranged. The workshop agenda included two panel sessions, each followed by a moderated discussion and audience questions.

Getting the Most out of NIH Meetings

Tamara Bavendam, M.D., M.S., Senior Advisor, Women's Urologic Health, KUH, NIDDK

Dr. Bavendam pointed out that the NIH convenes meetings to (1) inform future research and (2) synthesize completed research. She illustrated an example of how a series of NIDDK meetings resulted in a funded consortium. The February 2013 Lower Urinary Tract Symptoms (LUTS) Prevention Think Tank brought together a small group of health professionals who had a vested interest in caring for people with LUTS to discuss prevention. In November 2013, a larger multidisciplinary group was convened for the Women's Urologic Health Research Program Planning Meeting to address prevention relative to other areas of women's urologic health. Prevention research emerged as a priority area to pursue and offered compelling arguments to secure funding for a funding announcement. The May 3–4, 2014, Path to Prevention of LUTS in Women: Bladder Health Workshop informed the request for application (RFA) for prevention of LUTS in women across their life course, which was published in August 2014. The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium was established in July 2015.

Dr. Bavendam elaborated on key messages related to establishing a career in urologic conditions and identified institutional resources and funding sources. The path to becoming a successful clinician scientist takes a great deal of effort. She recommended that attendees pursue research that excites them and communicate their ideas to program officers early. Across a career in urology, conducting research will require multiple federal and nonfederal funding sources. Nonfederal funding sources, including insurance companies, support experiments to collect preliminary data. The Urology Studies in NIDDK Repository houses clinical data and specimens and is a resource for generating preliminary data. In addition to the NIH, other federal funding sources include the Agency of

Healthcare Research and Quality, the Department of Defense, and the U. S. Department of Veterans Affairs (VA), among others.

Dr. Bavendam summarized the grant process from publication of Funding Opportunity Announcement to funding of a grant. Details can be found in this document's Appendix .

The NIDDK wants to (1) receive applications that align with its mission, (2) maintain a favorable payline, (3) develop researchers who will become established NIDDK investigators, and (4) build interdisciplinary teams. The investigator-initiated research—the R01 category—comprises the largest percentage of the NIDDK budget; training grants are avenues to build the R01 pool.

Dr. Bavendam encouraged participants to base their research direction on the work they are passionate about and trained to do, seek out collaborators, and determine the availability of resources at their respective institutions. She recommended that attendees develop the specific aims of their research and communicate with program officers prior to applying. Dr. Bavendam challenged the audience to think about the qualities common to strong candidates for research careers, including curiosity, need for variety, ability to take criticism, patience, and persistence.

Panel I: Balancing Research and Clinical Care

Moderator: Tracy Rankin, Ph.D., Deputy Director, KUH, NIDDK

Dr. Tracy Rankin, a program officer in the NIDDK, remarked that the panelists' experiences have equipped them to speak about balancing a research career and a clinical appointment.

Making It Happen: Your Research Career

Linda Brubaker, M.D., Professor, Reproductive Medicine, University of California at San Diego

Dr. Linda Brubaker told early stage investigators (ESIs) that research careers are feasible and enumerated key factors for establishing a research career: flexibility, daily habits, clear priorities, understanding the role, and aligning with and learning from successful researchers. Regarding flexibility and daily habits, participants were told to be open to what is possible, be observant, and be curious. Dr. Brubaker recommended that participants listen to signals from within themselves as they discuss their research ideas, be open to all possibilities, and be curious to take full advantage of the broad range of experts available. Participants should perform research-related activities as a daily routine. To establish clear priorities, they should survey the data from their lives to determine whether it is consistent with their priorities. Dr. Brubaker suggested that participants look carefully at the invitations they accept, including writing tasks and research opportunities, and look at the patterns of successful researchers to establish synergy. She emphasized that a researcher's role is to be accountable, reliable, a person of quality and innovation, and responsive to others. Aligning with successful researchers involves developing a personal set of best practices based on the lessons and practices observed in others' work. Dr. Brubaker suggested using "prioritized time" rather than "protected time" to better translate the need for research-focused time to to department chairs and deans. She also recommended relaying any return on investment and how the prioritized research time will benefit the department and the institution, broadly.

Establishing a Career in Clinical Urology Research

Leslee Subak, M.D., Professor and Chair, Obstetrics and Gynecology, Stanford University School of Medicine

Dr. Leslee Subak detailed steps for navigating a career path and shared words of wisdom. Mentors and mentorship are critical to a person's career, and skills that complement those a researcher already has should be considered. She recommended that attendees be flexible, opportunistic, and creative. Dr. Subak described an example of a creative idea regarding obesity and UI that began as a small-scale study, which led to a larger multi-departmental collaborative effort with an outcome that catalyzed many new ideas. She encouraged participants to consider institutional funding and grants from professional societies in addition to NIH funding. Participants also were

encouraged to understand the requirements and expectations for a promotion within their institutions and work to achieve them. Dr. Subak remarked on being a proponent of life balance, not just work-life balance. She recommended that attendees be where they are needed when they are needed, learn to say no at the appropriate time, and decide how they will prioritize their time.

Establishing a Career in Basic Urology Research
Adam Klausner, M.D., Associate Professor, Division of Urology, Virginia Commonwealth University

Dr. Adam Klausner introduced his concept, a triangle of basic science success in which the clinical problem resides at the center and the three sides represent collaboration, cost, and commitment. The clinical problem that Dr. Klausner has addressed throughout his research career is the low amplitude rhythmic contractions (LARCs) often observed during urodynamics filling. The research questions being addressed are the causes of LARCs, whether LARCs are associated with voiding dysfunction, and how to quantify LARCs. After identifying a clinical problem, the next step was to find collaborators internal or external to Virginia Commonwealth University. Dr. Klausner recommended developing a collaboration sales pitch that defines the clinical problem, the effects on health, and the ways it can benefit the collaborator. He encouraged attendees to consider establishing a team of partners by reaching out to people in different disciplines who can address their research needs. In general, a potential collaborator should have a track record of proven success, a track record of mentorship or teaching, and laboratory space and resources to support the proposed work.

Dr. Klausner pointed out that the cost of doing research can be challenging for ESIs, whose funds often are limited. He recommended that listeners reach out to collaborators and other departments for available shared resources, including research animals. Personnel costs can be reduced by considering medical residents for 6-month project rotations, as well as summer students recruited through the institution's outreach programs and research awards. Seed funding from universities and grants from professional societies also are options to consider. Regarding commitment, a researcher in a clinical setting would need 1 to 2 days per week dedicated to research, especially ESIs. A balance of work and home also is essential. Dr. Klausner encouraged participants to be assertive in identifying key competitors, reviewers, and editors at scientific meetings and always have a scientific elevator pitch ready.

Dr. Klausner dedicated his talk and research career to the memory of his mentor and fellowship director, Dr. William D. Steers.

Establishing a Career in Urologic Health Services Research
William Stuart Reynolds, M.D., M.P.H., Assistant Professor, Department of Urologic Surgery, Vanderbilt University

Dr. William Stuart Reynolds enlightened participants on the many aspects of health services research (HSR) and a urologic HSR career. The main concepts included in HSR are access to care, cost of care, quality of care, health systems, and population health. Within the spectrum of translational science, HSR involves translation to practice and translation to community. A broad range of methods is included in HSR, such as comparative effectiveness, decision analysis, and health-related quality of life measures. Dr. Reynolds emphasized that, ideally, the physician/surgeon-scientist's work balance would be distributed equally between clinical, research, and administrative duties. He explained that as an academic urologist, physician-scientist, and Mentored Patient-Oriented Research Career Development (K23) Award recipient, 75 percent of his time is spent on research and career development activities. The remainder is spent on clinical duties and, to a lesser extent, administrative duties. Dr. Reynolds shared ways he tries to maintain this balance in work. First, clinical efforts should be focused and narrow, while maintaining the highest level of patient care. Second, the research also should focus on a narrow direction, and roles and responsibilities for the research team should be established. He recommended that listeners trust the clinical and the research teams to do their jobs. Third, administrative duties, such as teaching or speaking engagements, also should be focused and not include extra commitments. Dr. Reynolds remarked that time management is key to maintaining a work balance. Developing a daily and weekly schedule and prioritizing

research are helpful. He encouraged participants to adapt as their research careers develop and new opportunities arise.

Moderated Discussion and Audience Question and Answer

Dr. Rankin asked the panel about strategies for addressing rejection of scientific papers and research proposals. Dr. Klausner explained that as one who graduated top of his class in medical school, academic rejection and failure was new to him. Had it not been for the encouragement of collaborators and mentors, he would not have been successful in research. He suggested keeping a file of research proposals that were not funded easily accessible for future reference. Dr. Subak pointed out that rejection of this type is part of every research career. Even the best idea can receive a meritorious score and still not be funded for many reasons, such as timing. She suggested engaging like-minded colleagues and mentors, continuously applying for research funding, and communicating regularly with funding agency program officers.

A participant remarked on the resistance to starting a research career because of the NIH starting salary cap and the 75 percent time investments required and asked the panel for suggestions on paying off college loans while supporting a reasonable lifestyle. Dr. Subak called attention to the NIH Loan Repayment Programs that helped her start her career more than 25 years ago. She encouraged attendees to take advantage of this opportunity if they are eligible. Regarding the NIH cap, Dr. Subak suggested that salaries of basic and clinical researchers should be the same and that basic researcher's salary should not reflect the NIH's pay scale. The contributions of clinicians and researchers may differ, but they are equal in stature. Academic institutions and medical centers could consider developing ways to bridge this gap in salaries. Fostering a culture that encourages collaboration and collegiality is one way to start. Dr. Rankin noted that 50 percent of urology surgeons' time is protected in the K08 Clinical Investigator Awards supported by the National Cancer Institute and NIDDK.

A participant commented on her 75 percent protected time as a urologic researcher who conducts research from a mentor's laboratory and covers 20 percent of the overall costs. She asked for suggestions on transitioning to an independent position and whether there were provisions for existing grants to support independent researchers working in shared laboratory space. Dr. Klausner recently acquired his basic science research laboratory after having conducted research for most of his career in a collaborator's shared space, an arrangement he found beneficial. Managing a research laboratory can be challenging for investigators new to a research career—starting in a shared laboratory environment brings advantages.

Dr. Heidi Brown, a K12 Scholar with 75 percent protected time, asked about real-world approaches to guard this time to remain accessible, yet not available (i.e., off limits), to the clinical staff. Efforts to avoid distractions—including scheduling two half-days for the clinic, versus one half-day, and undertaking operating room duties every other week—have not been the best solutions, she added. Dr. Reynolds suggested empowering the clinical staff to make decisions that the clinician would support, setting up specific no-call zones, relaying to staff what clinicians are doing so that the staff will help to minimize distractions, and protecting time. The goal is to set the expectations and priorities early on.

Another participant remarked that the division directors and colleagues could support a clinician's protected time, cover their duties in nonemergency situations, and vice versa. The participant emphasized conveying needs to staff and colleagues for preparing funding applications and proposals. Dr. Brubaker suggested experimenting with fixed times for returning calls; addressing administrative duties; and rewarding, incentivizing, and acknowledging staff who help achieve these goals. Dr. Klausner commented that academic medicine requires commitments to move the science forward; those roles should be established and made known. He also commented that relocating an office temporarily to a remote place on campus could help.

A participant asked about compelling arguments for maintaining protected time as the end of an award cycle moves closer. Dr. Subak pointed out the following: (1) research is critical to a department's status and respect in the academic community, which a clinician shares; (2) an ideal scenario would be to support junior faculty for 5 years

or more with the NIH K12 funding mechanism; (3) investments in people who are most likely to be successful and research that is most promising is key to maintaining the pipeline; and (4) ESIs should detail their successes and value to the department and the institution. Dr. Brubaker added that annual conversations with department chairs and division directors will ensure that expectations and metrics are aligned and that researchers' accomplishments and progress are identified so that these leaders can pitch the researchers' portfolios. Dr. Klausner cautioned against relying solely on department leaders to be advocates—they may not be up to date with investigators' research. Instead, he recommended that attendees look for opportunities to engage the dean and others in influential positions and use metrics that are familiar to all parties. Another participant suggested engaging staff in the research process, which could spark their interest in a project.

Panel II: Path to Funding for New Researchers

Moderator: Jenna Norton, M.P.H., Program Manager, KUH, NIDDK

Ms. Jenna Norton explained that time has been set aside at this pre-meeting workshop to highlight the various funding opportunities within and outside the NIH that may be relevant to research on benign urologic conditions. She noted that some, but not all, funding sources would be highlighted in this panel. The KUH hopes that the information will be a helpful starting point to assist ESIs in thinking broadly about potential funding opportunities.

Funding Opportunities in Benign Urologic Conditions at the NIDDK

Tracy Rankin, Ph.D., Deputy Director, KUH, NIDDK

Dr. Rankin described the NIDDK mechanisms for research training and career development, which include two categories of postdoctoral training mechanisms: individual level and institutional level. The institutional training grants provide two options: the Ruth L. Kirschstein Institutional National Research Service (T32) Award (NRSA) for researchers with Ph.D.'s or M.D.'s and the Multidisciplinary K12 Urologic Research (KURe) Career Development Program for M.D.-Ph.D. holders. The individual training grants include the Individual Postdoctoral NRSA (F32) for Ph.D. or M.D. holders, K08 and K23 grants for those with clinical degrees, K01s for Ph.D. or non-licensed M.D. holders, and K99/R00 fast track awards. The NIDDK uses the Small Research Grant (R03) to supplement the K awards of trainees who are transitioning to independence. Most medical residents and fellows submit applications for F32s, and junior faculty and fellows submit applications for K awards. The NIDDK supports researchers at different career transitioning points with programs and activities, including the Loan Repayment Program, career development workshops, and generous paylines to ESIs. Dr. Rankin emphasized that a large percentage of researchers funded through the training mechanism subsequently receive an R01 and reminded participants of NIDDK's urology mission.

Funding Opportunities in Benign Urologic Conditions at the National Institute on Aging (NIA)

Marcel Salive, M.D., M.P.H., Health Scientist Administrator, Division of Geriatrics and Clinical Gerontology, NIA

Dr. Marcel Salive provided an overview of the funding opportunities in the NIA for urology researchers and encouraged participants to subscribe to *Inside NIA: A Blog for Researchers* to stay current on funding, career, and scientific information. Dr. Salive noted the NIA mission to improve the health, well-being, and independence of adults as they age and highlighted two relevant funding opportunities for ESIs that are unique to NIA. The Grants for Early Medical/Surgical Subspecialists' Transition to Aging Research (GEMSSTAR) award is an R03 pre-K award for junior faculty physicians to launch a research career that bridges their subspecialty (e.g., traditional medicine, surgery, or dentistry) and aging. The $75,000, 2-year award is contingent upon securing support for a professional development plan that will run concurrently. Scientific and career conferences for GEMSSTAR Scholars are held biannually, solicitation receipt dates occur annually in the fall, and 15 grants are awarded annually. The Paul B. Beeson Emerging Leaders Career Development Award (K76) in Aging supports talented scientists prepared to take an active leadership role in transformative change that will lead to improved health care outcomes. The RFA set aside is $225,000 per year for 3 to 5 years. The NIA research planning and initiatives

include scientific concept approvals (i.e., RFAs), general FOAs, and the NIA blog. Additional details on aging-related urology funding opportunities can be accessed from the NIA website.

The National Institute of Nursing Research (NINR) Funding Opportunities in Chronic Conditions
Karen Huss, Ph.D., R.N., Self-Management Branch, NINR

Dr. Karen Huss called attention to the NINR mission to promote and improve the health of individuals, families, and communities. As a disease agnostic (i.e., not focusing on any one disease), the NINR supports and conducts clinical and basic research and research training on health and illness at all stages of life. NINR's areas of scientific focus—including symptom science, wellness, self-management, end-of-life and palliative care, training, and technology—are outlined in the NINR Strategic Plan. Research in the Self-Management Branch aims to improve strategies to assist individuals with acute and chronic conditions and their caregivers, health care professionals, and communities to better understand and manage illness and health behavior. Dr. Huss explained that the NINR supports nurses and non-nurses, and she reviewed the current FOAs that are relevant to urology research. She highlighted two chronic condition research projects focused on UI: Translating Unique Learning for Incontinence Prevention and Web-Based Self-Management Intervention for Intermittent Urinary Catheter Use. Dr. Huss remarked that the chronic conditions science of the future will focus on translating scientific evidence-based interventions to community and home settings, working and partnering with communities, promoting use of available technologies, employing the use of self-management in the context of multiple comorbid conditions, and biopsychosocial approaches. Participants were referred to NINR's website for additional details on funding.

Funding Opportunities in Benign Urologic Conditions at the National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Michael Wolfson, Ph.D., Division of Discovery Science and Technology, Program Director, NIBIB

Dr. Michael Wolfson pointed out that the NIBIB fulfills its mission to improve health by leading the development of and accelerating the application of biomedical imaging and bioengineering technologies. Details of active funding opportunities, program officers, funding mechanisms and policies, and funded research are accessible from the NIBIB website. Dr. Wolfson pointed out that the NIBIB is disease agnostic; therefore, funding opportunities are categorized by technology development areas. The Division of Discovery Science and Technology supports drug delivery systems and devices and biologics immunoengineering, as well as biomaterials and biosensors. One program area, the Division of Interdisciplinary Training, is dedicated to training grants. He emphasized that the NIBIB supports non-hypothesis driven research in its R01 Bioengineering Research Grants. The applicants must identify the unmet need and justify how the technology being developed or accelerated will address that need. The Bioengineering Research Project (U01) is a path to translation that supports principal investigators experienced in managing complex projects. In addition, the Exploratory/Development (R21) funding mechanism is used to support NIBIB-specific, not parent, R21 grants for novel biomedical research approaches in which there is no preliminary data, as well as a new investigator-only Trailblazer award.

Funding Opportunities in Benign Urologic Conditions at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Donna Mazloomdoost, M.D., Medical Officer, Project Scientist for Pelvic Floor Disorders Network, Gynecologic Health and Disease Branch, NICHD

Dr. Donna Mazloomdoost stated that NICHD's mission is to ensure that every person is born healthy and wanted; women suffer no harmful effects from reproductive processes; and all children have the chance to achieve their full potential for healthy and productive lives. The Institute also aims to ensure the health, productivity, independence, and well-being of people through optimal rehabilitation. She explained that NICHD's historical paylines for R01s have been declining steadily since the NIH budget doubling between 1998 and 2003, and the funding success rates have declined over time, partly due to the nature of human subjects research to demand higher budgets, which poses a challenge to funding new innovative projects. To address this issue, the NICHD is moving away from the strict payline approach. Each branch will identify research gaps and priorities and will have the flexibility to fund

projects that best align with these priorities. Currently, the NICHD supports the R funding mechanisms (e.g., R01, R03, and R21), the NRSA, and Mentored K awards, including the K12 Building Interdisciplinary Research Careers in Women's Health (BIRCWH). In addition, the Gynecologic Health and Disease Branch supports basic, clinical, and translational research programs related to gynecological health throughout the reproductive lifespan, including the pelvic floor disorders (PFD) program; the Pelvic Floor Disorders Network; high-priority research areas, including investigating the genomic impact on gynecological conditions; and low-priority research areas, such as incontinence. She called attention to the NICHD-specific funding mechanism restrictions that apply to parent Clinical Trial R01s and encouraged participants to contact program officers before applying. She highlighted active FOAs that are relevant to urology—including stem cell research for pelvic organ prolapse, probiotics, and human microbiome research—and the Support of Competitive Research Program, which supports investigators working in low-resource institutions.

Funding Opportunities in Benign Urologic Conditions at the National Center for Complementary and Integrative Health (NCCIH)
Lanay Mudd, Ph.D., Program Director, Division of Extramural Research, NCCIH

Dr. Lanay Mudd provided an overview of the NCCIH, which aims to define the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care for a wide variety of diseases. Two categories of research and the associated outcomes are funded: (1) mind and body practices, such as acupuncture, and (2) natural products, including diet supplements. The NCCIH encourages investigators to identify the building blocks of mind and body clinical trials prior to performing safety and efficacy studies to ensure that the study is well designed and that the research team necessary to do the work will be in place. In addition, a framework for human subjects research has been developed that expands from the basic mechanistic science to pragmatic studies and funding mechanisms to support each phase. The parent R01, R21, or R15 is available to support basic science. Translational studies are supported by the Single-Site Investigator-Initiated Clinical Trial (R61/R33) awards. Intervention, refinement, and optimization studies for mind and body mechanistic and natural products clinical studies are supported by the Exploratory/Development Phase II (R33) or Cooperative Agreement (U01) mechanisms. The efficacy or effectiveness and pragmatic trials are supported by the larger funding mechanisms, such as the Cooperative Agreements (UG3/UH3 or U24). Details on resources and funding and guidance on use of pilot studies can be accessed from the NCCIH website.

Funding Sources Beyond NIH: A Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) -Funded Research Project
Rahel Nardos, M.D., Assistant Professor, Urogynecology/Obstetrics and Gynecology, Oregon Health & Science University (OHSU), School of Medicine

Dr. Rahel Nardos shared her experience in securing non-NIH funding to support her research on understanding the pathophysiology of overactive bladder (OAB) and urgency urinary incontinence. In her current role as OHSU assistant professor, Dr. Nardos holds a 60 percent clinical and 10 percent administrative appointment with Kaiser Permanente Northwest and a 20 percent research and 10 percent administrative appointment with OHSU. She highlighted two funding sources: the Pfizer, Inc., LUTS-OAB Competitive Grant and the SUFU overactive bladder syndrome (OABS)-LUTS. Dr. Nardos received the Pfizer, Inc., LUTS-OAB 2-year Competitive Grant during her 2008–2011 OHSU urogynecology fellowship. The aim was to better understand the role of the brain in normal and abnormal bladder function. Findings from this work were published in 2013 and 2015.

The SUFU and its foundation support research and development efforts of urology residents, fellows, and junior faculty—those with less than 5 years of training. Applicants must be SUFU members or work with a faculty mentor who is a member and must present findings at a winter SUFU meeting. The grants are 2-year awards, and opportunities for funding include studies on chemodenervation, neuromodulation, OAB fecal incontinence, and OAB LUTS. Dr. Nardos received the 2015–2017 SUFU OABS-LUTS award for her project titled "The Role of Urinary Microbiomes in Women with Urgency Urinary Incontinence." She noted that the non-NIH funding does not include indirect costs and would need to be supplemented with institutional funding, which can occur only in an

academic setting. Transdisciplinary collaboration is one way to maximize the benefits of smaller grants, but she recommended that attendees continue to apply for NIH funding.

Funding Sources Beyond NIH: An American Urogynecologic Society (AUGS) -Funded Research Project
Vivian Sung, M.D., Associate Professor, Obstetrics and Gynecology, Women & Infants Hospital, Alpert Medical School, Division of Urogynecology, Brown University

Dr. Vivian Sung outlined her research training background. At the start, she received a T32 training fellowship to work in epidemiology and clinical trials, followed by an NICHD K12 Women's Reproductive Health Research Career Development award from 2006 to 2009 to focus on epidemiologic research and decision-making outcomes. Dr. Sung received an AUGS Foundation Grant in 2008 to explore alternative ways to measure patient reported outcomes (PRO) and subsequently a K23 Award that focused on patient-centered outcomes and research. Dr. Sung elaborated on her 2008 AUGS Foundation grant that applied Patient-Reported Outcomes Measurement Information System (PROMIS®) measures to female PFD. Conceptualizing and interrogating three specific aims provided preliminary data for an R21 to investigate tailored measures for female UI. A multidisciplinary team was established that consisted of a psychometrician, a survey methodologist, a computer informatics specialist, and urogynecologists. The goal was to develop PRO measures for UI using innovative survey methods. Outcomes were development of an item bank, calibration and validation of PRO in female UI, and other downstream research.

Dr. Sung described the 2018 AUGS PFD Research Foundation awards and eligibility requirements. Applicants can submit proposals for a Fellow Research Award, Faculty Research Award, the June Allyson Memorial Fund Research Award, or the dual PFD-Interstitial Cystitis Association (ICA) interstitial cystitis (IC)/Painful Bladder Syndrome (PBS) Research Grant. The PFD-ICA IC/PBS is a 1-year award; all others are 2-year awards. Active AUGS members are eligible to apply and are required to have a senior mentor or mentoring team. Fellows (e.g., M.D.'s or Ph.D.'s in postdoctoral fellowships) will need to ensure that the grant remains with the institution. Junior faculty are required to demonstrate institutional support for the needed time. The application consists of a 5-page NIH-style biosketch, abstract, candidate information, research plan, and letters of support from mentors and co-investigators. One application is allowed per funding cycle, and the 2018 application deadline is March 1. In closing, Dr. Sung shared a research career to-do list that included applying for other grants to support preliminary work, seeking out appropriate mentorship, developing expertise in a niche, letting the research findings guide the research path, and seeking out opportunities to advance in national societies.

Funding Sources Beyond NIH: An American Urological Association (AUA) -Funded Research Project
A. Lenore Ackerman, M.D., Ph.D., Assistant Professor, Surgery, Division of Urology, Cedars-Sinai Medical Center

Dr. A. Lenore Ackerman presented her pathway to independence in research. In a roundabout journey, Dr. Ackerman received an undergraduate fellowship from the American Heart Association, an F31 individual NRSA from the National Institute of Allergy and Infectious Diseases to support predoctoral studies, and a National Medical Scientist Training Program Basic Science Research Award during medical school. She received an AUGS Physician-Scientist Training award during her residency and was an AUA Urology Care Foundation Scholar. Dr. Ackerman's current funding includes a SUFU Chemodenervation Grant, University of California, Los Angeles, Clinical and Translational Science Institute Core Voucher Award, Cedars-Sinai Eigler-Whiting-Mann Award, and Department of Defense Congressional Research Peer-Reviewed Research Program Discovery Award. These successful funding awards resulted from submitting more than 15 applications or proposals within the past 18 months. Dr. Ackerman emphasized the value of advocates and sponsors, as well as mentors, to a successful research career. She acknowledged the many mentors, advocates, and advisors who have helped her career.

Moderated Discussion and Audience Question and Answer

Dr. Theodore Johnson pointed out the role of the VA in assisting investigators with their research careers. He also asked Dr. Mudd about the name change from the National Center for Alternative and Complimentary Medicine to

the NCCIH. Dr. Mudd explained that the name change reflects an integration of so-called “alternative” practices or methods into mainstream medicine.

A participant asked the program officers about strategies for submitting a proposal for multidisciplinary research that would be relevant to more than one IC. Dr. Rankin replied that the applications should be focused and not necessarily span ICs, but communication with program officers to identify the best fit would be critical. A primary IC must be indicated on the application. Dual assignments can be requested, although they are not practical in this budget climate. Dr. Wolfson added that the aims and the source of the innovations for applications submitted to the NIBIB are what drives the decision on whether NIBIB accepts the project for consideration. He reiterated the importance of contacting program officers. Dr. Mudd suggested framing the aims to fit the IC’s mission or strategic plan and submitting it to the respective program officers. The enthusiasm generated would be an indicator of the potential IC to pursue further. Advice will help your application, and a “no” response to an application is not a “no” to the science or idea. Dr. Salive noted that the NIA supports secondary applications using discretionary funds, which are limited. Bridge funding (R21 to R56) options to support pilot studies also could be applied. Dr. Huss explained that NINR’s funding decisions are based on the science (i.e., scientific idea), rather than an established payline and emphasized the need to align applications with the goals and priorities addressed in the strategic plan of each IC. Submitting concept papers with the application and searching the NIH Research Portfolio Online Reporting Tool for information on funded grants would be helpful, as would searching the ICs’ FOAs.

A participant asked Dr. Wolfson at which phase in technology development a new device will be ready to transition to other ICs and the Small Business Innovative Research (SBIR) program. Dr. Wolfson replied that NIBIB’s interest statement is listed within each FOA. The NIBIB supports Phase I trials, and that support ends at the first in-human trials of the demonstrated technology. Refinement and optimizations for clinical use are supported by other ICs. If the challenge to be addressed in the grant is not related to the engineering of the device, but rather is focused on the use of recently-developed technology, then applicants should discuss their project with program staff in the most relevant Institute or Center.

Dr. Rankin emphasized communicating with program officers a minimum 10 to 12 weeks in advance of applying or submitting a proposal for funding.

Dr. Jonathan Beckel wondered about opportunities across the career life cycle for Ph.D. basic scientists who are interested in urology research. Dr. Rankin called attention to the NIDDK-supported George M. O’Brien Urology Cooperative Research Centers, which focus on basic urology research concepts. Each center has a Pilot and Feasibility Program that sponsors opportunity pool grants for pilot studies. In addition, the NIDDK K12 Program is open to Ph.D. and M.D. applicants. Dr. Huss pointed out that another option for researchers is a diversity supplement, which is sponsored by many of the ICs.

Dr. Klausner noted that the O’Brien Center principal investigators have been invited to the 2018 SUFU meeting to discuss resources that are available to the community and encouraged participants to consider attending.

Appendix: Know Your NIH Alphabet Soup!

Glossary of Key NIH & NIDDK Funding Terms

Selected Funding Mechanisms at NIH and NIDDK

R01 – Research Project Grant: The R01 grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH. R01s are typically awarded for one to five budget periods and can be investigator-initiated or can be solicited via a Request for Applications. Learn more: https://grants.nih.gov/grants/funding/r01.htm

NIH parent R01s include:

- NIH Parent R01 (PA-16-160) – ***can no longer be used for clinical trials***: https://www.niddk.nih.gov/research-funding/current-opportunities/pa-16-160
    - 23 participating Institutes and Centers, including NIDDK, NIA, NIBIB, NICHD & NINR
- NIH Parent R01 – Clinical Trials Required (PA-18-345): https://grants.nih.gov/grants/guide/pa-files/PA-18-345.html
    - 14 participating Institutes and Centers, including NIA & NINR
    - NOTE: Some NIH Institutes (including NIDDK) have an Institute-specific Clinical Trials R01, and Institute-specific funding paths for multi-center trials.

*__Clinical Trials__ are research studies in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. https://grants.nih.gov/policy/clinical-trials/definition.htm

NIDDK R01 applications may be submitted through the following mechanisms:

- The NIH Parent R01 (PA-16-160) – ***can no longer be used for clinical trials***: https://www.niddk.nih.gov/research-funding/current-opportunities/pa-16-160
- NIDDK Clinical Trials Required R01 (PA-18-330). This is ONLY for studies with 1 or 2 research centers. NIDDK __does not__ accept applications to the NIH Parent R01 – Clinical Trials Required (PA-18-345): https://grants.nih.gov/grants/guide/pa-files/PA-18-330.html
    - NOTE: NIDDK clinical trials with more than two research centers cannot be submitted as an R01 and must be submitted as a U34 (Implementation Planning Cooperative Agreement), followed by a U01 (Research Project Cooperative Agreement): https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms/u34-multi-center-clinical-studies

R03 – NIH Small Grant Program: The R03 grant mechanism supports small research projects that can be carried out in a short period of time (up to two years) with limited resources (direct costs of up $50,000 per year). Learn more about the NIH R03 mechanism: https://grants.nih.gov/grants/funding/r03.htm

NIH Parent R03 (PA-16-162): https://grants.nih.gov/grants/guide/pa-files/PA-16-162.html

- 11 participating Institutes and Centers, including NIA, NIBIB & NICHD

NIDDK does not accept R03 applications in response to the Parent R03 FOA. NIDDK limits use of the R03 mechanism to defined research areas specified in published program initiatives, which may be found by searching NIDDK funding opportunities: http://www2.niddk.nih.gov/Funding/FundingOpportunities/

R21 – Exploratory/Developmental Research Grant Award: The R21 grant mechanism is intended to encourage exploratory/developmental research by providing short-term (up to two years) support for the early and conceptual stages of project development. The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year. Learn more about the NIH R21: https://grants.nih.gov/grants/funding/r21.htm

NIH Parent R21 (PA-16-161): https://grants.nih.gov/grants/guide/pa-files/PA-16-161.html

- 17 participating Institutes and Centers, including NIA, NICHD & NINR

NIDDK does not accept applications in response to the NIH Parent R21 Funding Opportunity Announcement (PA-16-161) or support basic science with the R21 mechanism. NIDDK limits use of the R21 mechanism to defined human clinical trials research specified in published program initiatives, which may be found by searching NIDDK funding opportunities: http://www2.niddk.nih.gov/Funding/FundingOpportunities/

Fs – Fellowships: An NIH training program award where the NIH specifies the individual receiving the award. Awardees may include national and international trainees at the undergraduate, graduate, and postdoctoral levels. Explore NIH F Awards (F05, F30, F31, F32, F33 & F99/K00): https://researchtraining.nih.gov/programs/fellowships

NIDDK Fs include F30s & F31s. Graduate students may be eligible for support from an NIDDK-funded individual fellowship (F31, diversity F31). Medical students enrolled in an MD-PhD program are eligible for fellowship (F30) support. Postdoctoral fellows and physician scientists in research fellowship training may be supported by fellowships (F32s) for up to three years. Learn more: https://www.niddk.nih.gov/research-funding/training-career-development

Ks – Career Development Awards (CDA): Awards for candidates who wish to further develop their careers in biomedical, behavioral and clinical research. Applicants are generally required to hold a research or health professional doctoral degree or its equivalent. Some Institutes limit eligibility to applicants with health professional doctoral degrees. Explore NIH Ks (K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K43, K76 & K99/R00): https://researchtraining.nih.gov/programs/career-development

> **NIDDK Ks** (K01, K08, K23, K25 & K99/R00) are available for Ph.D. researchers and physician scientists just beginning their faculty appointments who have protected time for research: https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms/k-awards

U01 – Research Project Cooperative Agreement: The U01 supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies, when substantial programmatic involvement is anticipated between the awarding Institute and Center. More information on the NIH U01 is available from: https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search_Type=Activity

> **NIDDK** supports investigator-initiated, multi-center clinical studies through a two-part process: an implementation planning phase (U34), followed by a cooperative agreement (U01) to conduct the study. A study is considered to be "multi-center" if three or more sites are involved in the actual conduct of the study. Learn more: https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms/u01

Ps – Program Project/Center Grants: Program project/center grants are large, multi-project efforts that generally include a diverse array of research activities. NIH Institutes and Centers issue funding opportunity announcements to indicate their interest in funding this type of program. Explore the NIH P series (P01, P20, P30, P50): https://grants.nih.gov/grants/funding/funding_program.htm#PSeries

> **NIDDK Ps** include Center Core Grants (P30), which support shared resources/facilities for use by multiple investigators to enhance collaborative, multidisciplinary research focused on a common problem or goal, and Specialized Centers (P50), which support activities designed to enhance multidisciplinary studies on a specific disease entity or biomedical problem area. Learn more:
>
> P30: https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms/p30
>
> P50: https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms/p50

Funding Opportunity Announcements

FOA – Funding Opportunity Announcement: A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program. https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/understand-funding-opportunities.htm

PA – Program Announcement: A PA is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes. NIH may also make funds available through:

- **PAR:** Program Announcement with special receipt, referral and/or review considerations.
- **PAS**: Program Announcement with Set-Aside Funds

RFA – Request for Application: A formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and awardees as well as joint responsibilities and obligations. Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

Parties Involved

IC – NIH Institute or Center

The NIH organizational component responsible for a particular grant program or set of activities. The terms "NIH IC" or "awarding IC" are used to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes

in the terms and conditions of award. See a list of all NIH ICs: https://grants.nih.gov/grants/glossary.htm#InstituteorCenterIC

PD/PI – Program Director/Principal Investigator: The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically.

ESI – Early Stage Investigator: A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award. A list of NIH grants that a PD/PI can hold and still be considered an ESI can be found at https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm.

EEI – Early Established Investigator: A Program Director / Principal Investigator (PD/PI) who is within 10 years of receiving their first substantial, independent competing NIH R01 equivalent research award as an Early Stage Investigator (ESI).

PO – Program Official/Program Officer/Project Officer: The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant. The PO has NO role in the review process.

GMS – Grants Management Specialist: An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

SRO – Scientific Review Officer: The NIH official who serves as the designated Federal official having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the SRG and the determinations and management of conflicts of interest.

Application Review & Scoring

CSR – Center for Scientific Review: The NIH component responsible for the receipt and referral of grant applications for review, as well as the initial review for scientific merit of most applications submitted to the NIH. Note: Some funding announcements will specify that the review will be done by the Scientific Review staff within the Institute itself.

eRA Commons – the Electronic Research Administration Commons: a virtual meeting place where NIH extramural recipient organizations, recipients, and the public can receive and transmit information about the administration of biomedical and behavioral research. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively.

IRG – Integrated Review Group: A cluster of scientifically related Study Sections. Applications reviewed by the CSR are often initially assigned at the IRG level and then subsequently assigned to a specific Study Section or Special Emphasis Panel. This two-stage assignment process provides the opportunity to gain a broad perspective of the areas of science covered by the IRG and to appreciate changes in emphasis and the emergence of new areas while ensuring each application is reviewed by the most appropriate review group.

SRG – Scientific Review Group: A peer review committee group of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications.

Impact Score: The impact score is the rating which is assigned to an individual application by an SRG, and designates the reviewers' assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. The impact score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Impact scores may be numeric (10 – 90) or alphabetical (ND, for example). Generally, the top half of the applications, based on reviewer scores prior to the SRG, are discussed in the review group and will receive a numeric impact scores. Those not discussed receive a ND.

Summary Statement: A combination of the reviewers' written comments and the SRO's summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations. All applicants

receive a summary statement. Those that are discussed in SRG also receive a summary of the SRG discussion generated by the SRO.

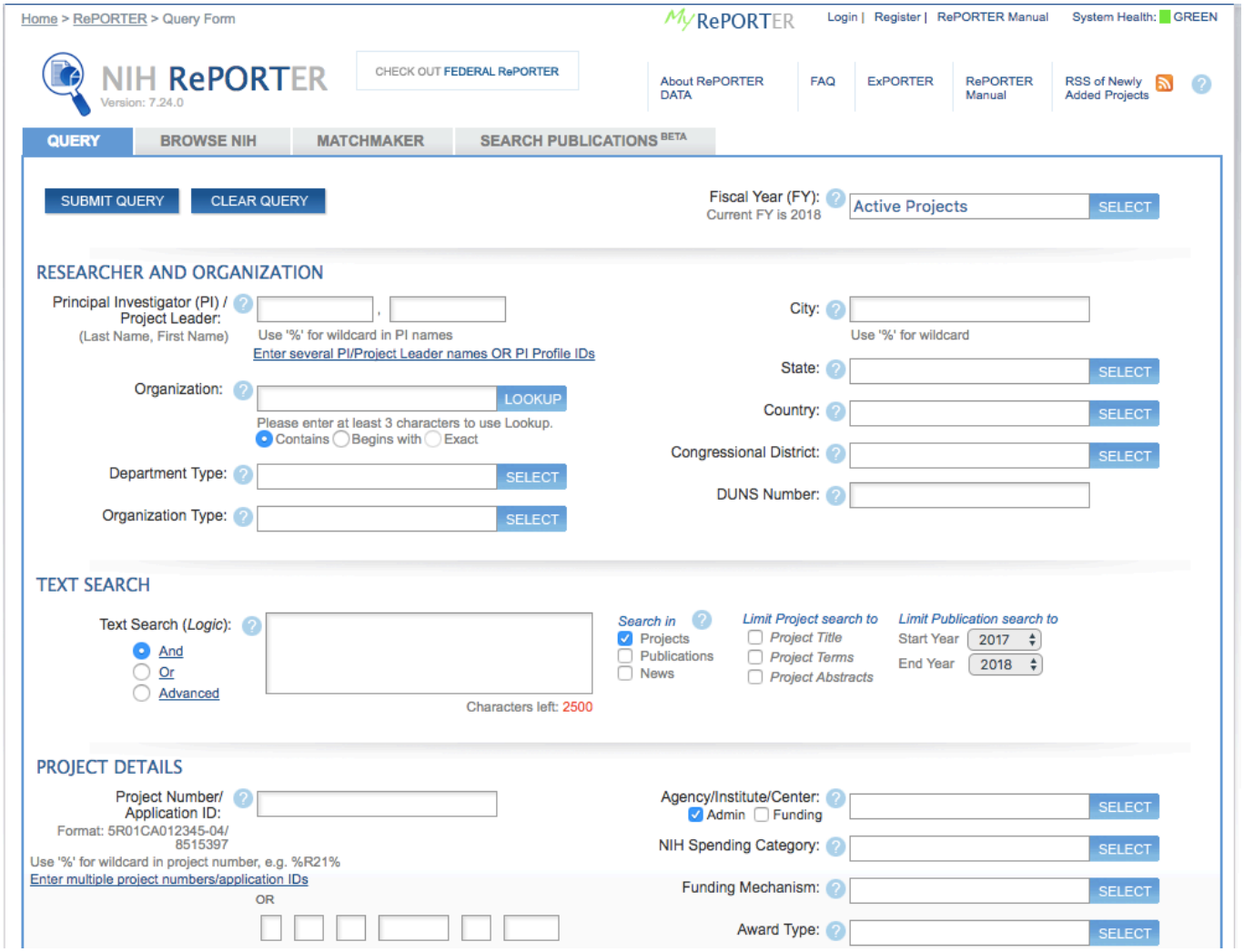
Payline: A percentile-based funding cutoff point determined by balancing the projected number of applications coming to an NIH Institute with the amount of funds available. Set after the budget is determined, paylines are not mandatory, are not made for all activity codes, and may be adjusted during the year. Paylines are Institute specific.

Percentile: Represents the relative position or rank of each impact/priority score (along a 100.0 percentile band) among the scores assigned by a particular study section. **In contrast to usual mathematical practice, a lower number indicates a better score.**

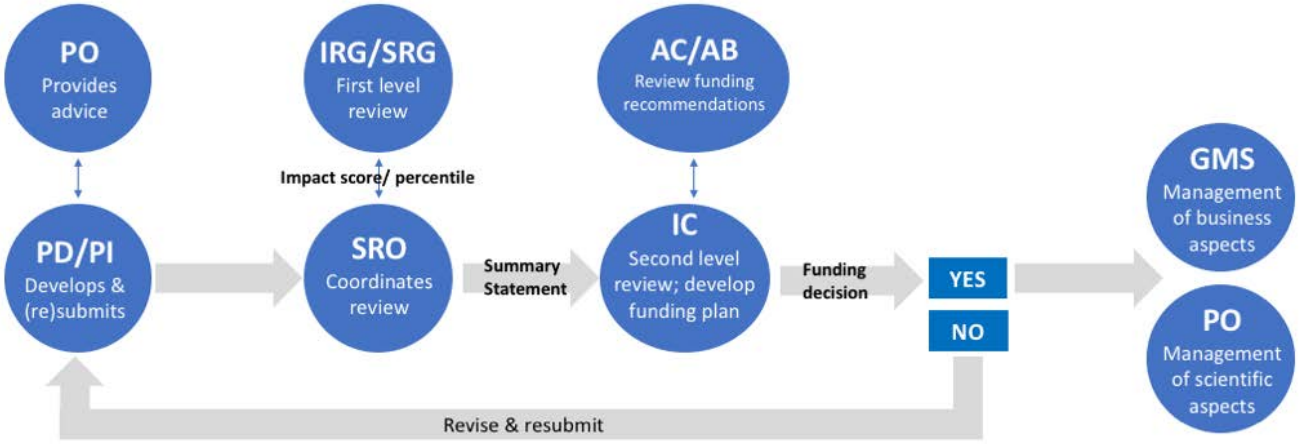
Resources

CTSA – Clinical and Translational Science Awards Program: CTSA supports a national network of medical research institutions — called hubs — that work together to improve the translational research process. CTSA Program support enables research teams including scientists, patient advocacy organizations and community members to tackle system-wide scientific and operational problems in clinical and translational research that no one team can overcome. Learn more about the CTSA program and find CTSA hubs: https://ncats.nih.gov/ctsa

NIH RePORTER – Research Portfolio Online Reporting Tools: NIH RePORTER provides access to reports, data, and analyses of NIH research activities. The tool allows you to search by NIH Institute or Center (IC) to understand what types of research each IC is funding. You can also conduct free text searches (e.g., "urinary incontinence" to see the scope of research funded in a specific area.



Grant Submission and Review Flow Chart: provides an overview of the grant submission process



PO: program officer, PD/PI: program director/principal investigator, IRG: integrated review group, SRG: scientific review group, SRO: scientific review officer, AC/AB: advisory council/advisory board, GMS: grants management specialist

NIH Grants Glossary & Acronym List. For a complete list of NIH terms and acronyms, visit: https://grants.nih.gov/grants/glossary