DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

221st Meeting of the NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

DIVISION OF DIGESTIVE DISEASES AND NUTRITION SUBCOMMITTEE Meeting Summary

Wednesday, January 25, 2023 Zoom Video Conference

Open Session

- 1) Dr. David Saslowsky opened the meeting by welcoming everyone.
- 2) The minutes of the September 7, 2022 subcommittee meeting were approved.
- 3) There were no DDDN Initiative Concept Clearances to discuss.
- 4) Dr. Stephen James provided an overview of the DDDN FY2022 awards. The following questions were asked:
 - **a) Question:** Does a prior R21 disqualify an applicant as a new investigator for an R01? **Answer:** No
 - **b) Question:** In the programmatic distribution, nutrition appeared to be the smallest category, why is that?
 - **Answer:** The Office of Nutrition Research (ONR) used to be a component of DDDN, but ONR has moved to the Office of the Director and now advises key officials in NIH leadership. While DDDN still has a close relationship with ONR, a lot of nutrition areas are assigned to that office rather than DDDN. Other reasons for the nutrition category appearing to be small is because obesity and nutrition are reported together, and a lot of diabetes research is being classified as nutrition for the Congressional spending but isn't categorized as such in the system used to create the report being presented today.
 - c) Question: Is the phase out of P01s only for DDDN or is that a broader issue across NIDDK or NIH?
 - **Answer:** This was a strategic decision by the NIDDK. Some other Institutes are doing this as well.
- 5) Dr. Saslowsky and Ms. Christine Densmore reviewed the DDDN Early Career Portfolio Analysis. The following questions were asked:
 - **a) Question:** Are there any implications of depicting only a small amount of Obesity and Nutrition grants being awarded within the division?
 - **Answer:** For Obesity and Nutrition, several related applications are funded in other DK divisions, especially DEM, and also many other NIH Institutes; DDN will continue to encourage applications from investigators conducting obesity and nutrition research, particularly in the early career development award space.

- **b) Question:** Noticing a decline in K01 funding percentages versus K08s and K23s, is there an expectation that the science be more developed for a PhD than it is for an MD? Or does it have to do with mentorship plans or both?
 - **Answer:** There is typically a higher research productivity expectation by peer reviewers for PhD K01 applicants, where 4 or more years of graduate training plus additional postdoctoral research has been focused exclusively on research. Also, more productivity is expected as years of postdoctoral research training as time of K01 application increases.
- **c) Question:** Health disparities and health equity are not listed under the active awards; is this because applicants are perhaps not labeling their research in that way?
 - **Answer:** This may be true as the framing of research aims in HE/HD terms is gaining broader acceptance.
 - **Comment:** This may be an opportunity to help refocus junior investigators to rethink about research that is being done and how it can be related to health disparities and health equities in a way that may not have been thought of previously.
- **d) Question:** What is the success rate prediction for K08s and K23s moving forward? **Answer:** We continue to follow the PIs of these awards and will continue to measure their success acquiring next-level NIH/NIDDK funding.
- **e) Question:** Are applications with a clinical trial component being tracked via AHRQ and PCORI?
 - Answer: Very important question that we will investigate and follow-up on.
- **f)** Comment: Would be beneficial to see how many R01s an individual applicant (post-training) is applying for and their overall success rate.
- 6) Dr. Saslowsky reviewed four DDDN Funding Opportunity Announcements and reminded everyone that current NIDDK funding opportunities can be found at https://www.niddk.nih.gov/research-funding/current-opportunities.
 - a) PAR-23-024: Catalyst Award for Early-Stage Investigators (ESIs) Pursuing Research on HIV Comorbidities, Coinfections, and Complications (DP1- Clinical Trial Optional).
 - **b)** RFA-DK-22-012: NIDDK Investigator Award to Support Mentoring of Early Career Researchers from Diverse Backgrounds (K26 Independent Clinical Trial Not Allowed).
 - c) RFA- DK-22-023: Ancillary Studies to the NIDDK Inflammatory Bowel Disease Genetics Consortium (R01 Clinical Trial Not Allowed).
 - **d)** NOT-OD-22-032: Notice of Special Interest (NOSI): Administrative Supplements for Research on Sexual and Gender Minority (SGM) Populations (Admin Supp Clinical Trial Optional).
- 7) Planned Workshops (more details can be found in the appendix):
 - a) Scientific Workshop on Expanding the Evidence Base in Gender-Affirming Care for Transgender & Gender Diverse Populations https://dpcpsi.nih.gov/sgmro/scientific-workshop-expanding-evidence-base-gender-affirming-care-transgender-and-gender will be held via webcast on March 27, 2023. The purpose of this workshop is to share what is known about clinical practices with the population, including the most recent scientific findings, and to identify crucial knowledge gaps and research opportunities for studies on transgender health and gender-affirming care across the life course.
 - b) Neural Plasticity in Energy Homeostasis and Obesity Workshop https://www.niddk.nih.gov/news/meetings-workshops/2023/neural-plasticity-in-energy-homeostasis-and-obesity will be held via webinar April 13-14, 2023. The purpose of this workshop is to bring together experts in the neural plasticity of central and peripheral circuits that control food intake, energy homeostasis, and metabolism in healthy and unhealthy states, such as obesity, to review the science, identify knowledge gaps regarding the functional plasticity within these circuits, and identify high priority areas of research that may lead to

- therapeutic advances for obesity and other disorders related to metabolic dysregulation and food intake.
- c) Interventional Studies in Pancreatitis: Recent Progress, Knowledge Gaps and Research Opportunities https://www.niddk.nih.gov/news/meetings-workshops/2023/interventions-for-pancreatitis will be held at the University Club in Pittsburgh, PA on July 26, 2023. This one-day workshop aims to inform investigators of new developments in the field and identify the knowledge gaps and research opportunities that might inform possible future funding initiatives for NIDDK.
- 8) Completed Workshops (more details can be found in the appendix):
 - a) Yet to be Chartered: Lymphatic System in Health and Disease https://www.niddk.nih.gov/news/meetings-workshops/2022/yet-to-be-charted-lymphatic-system-in-health-and-disease was held via webinar on September 19 20, 2022. The objective of this meeting was to have international experts discuss current research, explore knowledge gaps, and identify opportunities in lymphatic disease research. Session topics included the state of research in lymphatics, lymphatic development and homeostatic function, lymphatics in inflammation and diseases of the gastrointestinal system, lymphatic dysfunction diseases, lymphedema, and the community's perspective: living with lymphatic disease and new technologies in lymphatic imaging and mapping. An executive summary was published on the NIDDK and NHLBI websites. A manuscript is in preparation for publication in JCI (Gaps and Opportunities in Lymphatic Research)
 - b) Housing and Obesity: Gaps, Opportunities, and Future Directions for Advancing Health Equity https://www.niddk.nih.gov/news/meetings-workshops/2022/workshop-housing-obesity was held via webinar November 14-15, 2022. The overall goal of this workshop was to accelerate research on the role of housing insecurity, including housing affordability, quality, stability, and its neighborhood context on behaviors and pathways underlying risk for obesity-related health disparities across the lifespan. The workshop emphasized existing research that connects housing policies and programs with obesity and methods for housing and obesity research, including study design, measures, data linkages and analytic approaches. An executive summary is in progress and will be posted on NIDDK's website.

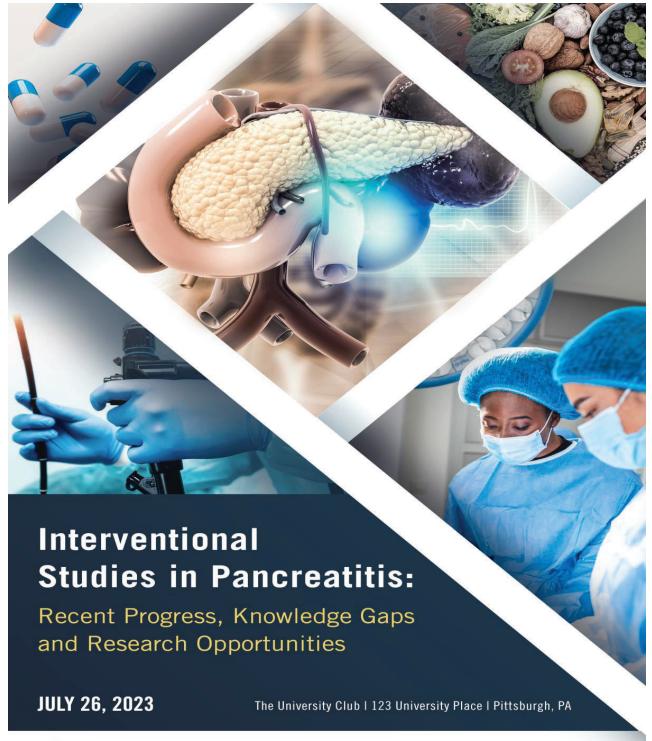
Closed Session

Council members reviewed competing applications. Four applicants with >\$1M in NIH funding (direct costs) were given special council review, one appeal and three budget restorations were reviewed. There were no foreign applications or skipped applications to review and vote on.

Comments and critiques regarding discussion topics and initiatives from council members are welcome and should be emailed to Drs. James and Saslowsky in advance of the next meeting.

-Appendix-

Planned Workshops





Rationale for Workshop

- Recent NIDDK Workshops have focused on the requirements for designing and conducting clinical trials in pancreatitis.
- The breadth and variety of interventions which are planned or underway include pharmacologic studies, nutritional studies and mechanical studies with devices, endoscopy and surgery.
- The purpose of this one day workshop is to inform investigators of new developments and to identify the knowledge gaps and research opportunities.

Organizing Committee

- Adriana Cowdin
- Sinead Duggan RD, PhD
- Phil Hart MD
- Padma Maruvada PhD
- Tonya Palermo PhD
- Jay Pasricha MD
- Kristen Roberts PhD, RD
- Jose Serrano MD, PhD
- David Whitcomb MD, PhD
- Dana Andersen MD

Randall Brand MD

Chris Forsmark MD

Steve Hughes MD*

John Neoptolemos MD

Steve Pandol MD

Anna Evans Phillips MD*

Jami Saloman PhD

Vikesh Singh MD, MPH

Dhiraj Yadav MD, MPH

^{*} Workshop Co-chairs

Workshop Agenda

- Keynote Speakers
 - Patient Advocate Patient Priorities
 - Investigator Overview of Knowledge Gaps
- Promising, New or Novel Bio-Pharmacol Interventions
 - Repurposing Approved Anti-inflammatory Drugs, Stem Cell Treatment, Chemical Ablation of Acinar Tissue
- Nutritional Interventions
 - Food as Medicine, Food as Causation, Oral versus Intrajejunal feeding, Alcohol Cessation Therapy
- Mechanical and Device Interventions
 - Intraductal Infusion of Drugs and Chemicals, Resection versus Excavation in Surgery, Timing and Subject Selection in Surgical Trials, Neural Device Studies

Workshop Logistics

Date and Venue

- Wednesday July 26, 2023 University Club, Pittsburgh PA
- The annual PancreasFest meeting will follow and will include a consensus meeting to identify standardized outcome measures to be used in pancreatitis trials

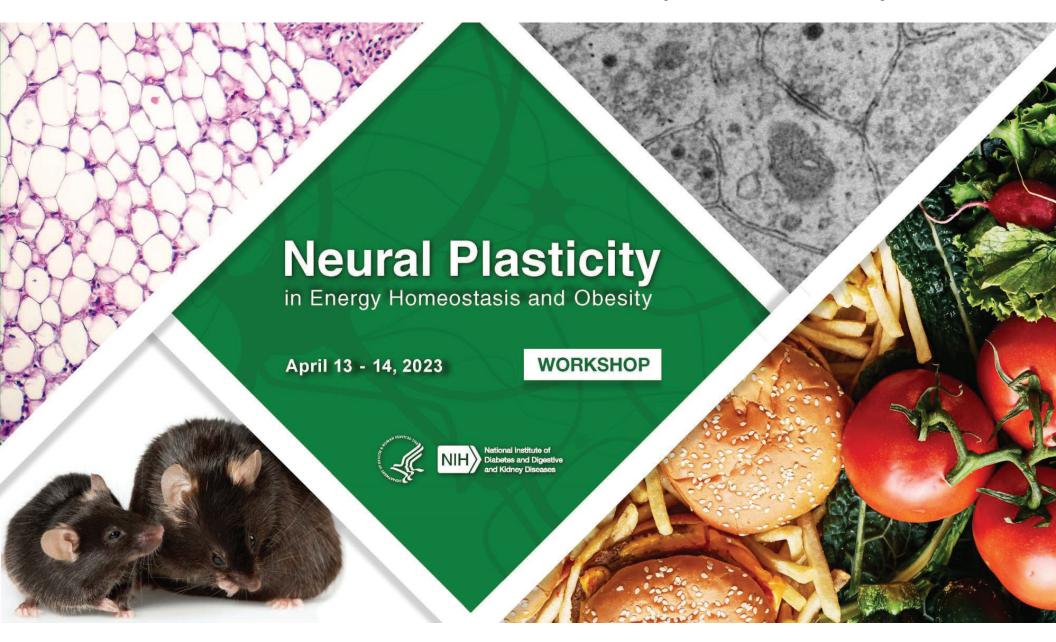
Registration

- Attendance is Free but On-Line Registration is Required
- Registration Access via NIDDK Website (Future Meetings)

Deliverables

- Conference Summary Manuscript to be published
- Recommendations May Inform Possible Future Funding Initiatives of NIDDK

Neural Plasticity in Energy Homeostasis and Obesity Workshop





Neural Plasticity in Energy Homeostasis and Obesity Workshop

Rationale

- Studying the functional connectivity of central and peripheral pathways that mediate energy homeostasis may reveal therapeutic targets for treating disorders related to food intake and metabolism, such as obesity.
- This 2-day, virtual workshop will examine the neural networks that control energy balance, focusing on bidirectional relationships between plasticity, metabolic state, and obesity.
- Session presentations, moderated discussions, and breakout groups will explore the state of the science and knowledge gaps.



Organizing Committee

Carrie Ferrario – University of Michigan

Heike Muenzberg-Gruening – Pennington Biomedical Research Ctr.

Linda Rinaman – Florida State University

Brad Cooke – DEM/NIDDK/NIH

Diana Cummings – DDN/NIDDK/NIH

Padma Maruvada – DDN/NIDDK/NIH

Andrew Bremer - NICHD/NIH

Dana Greene – OBSSR/NIH

Luke Stoeckel - NIA/NIH



Workshop Agenda

- Overview of Neural Systems that Control Food Intake and Energy Balance – Alan Watts
- Plasticity in Chemosensory Signaling
 - Gustatory Plasticity; Diet, Taste & Nutrition; Olfactory Perturbation & Obesity; Taste Signaling & Obesity
- Plasticity in Visceral Sensory & Humoral Pathways
 - Central Circuits Mediating Food Cues; Microbiota-driven Neural Plasticity; Vagal & Spinal GI Circuits; Neuropod EEC-mediated Vagal Transmission
- Plasticity in Autonomic & Hormonal Pathways
 - Central and Peripheral GLP1 Signaling; Development of Homeostatic Neural Circuits; Pancreatic Vagal Innervation & Glucose Homeostasis; Sympathetic Innervation of Adipose Tissue



Workshop Agenda

- Energy Sensing & Homeostasis: CNS Circuits
 - Diurnal Patterns, Feeding, & Metabolism;
 Hypothalamic Role in Energy Sensing; Hypothalamic Plasticity & Obesity; Hypothalamus & Metabolic Adaptation to Exercise
- Neural Plasticity in Feeding-Related Learning & Memory
 - Mesolimbic/Cortical/Dorsal Striatal Pathways; Diet-Induced Plasticity in Frontal Cortex; Metabolic State-Dependent Learning
- Cellular Regulators of Neural Plasticity
 - Hormonal Signaling & Glia in Feeding Control; Role of BDNF in Energy Homeostasis; Glial and Cerebrovascular Contributions to Metabolic Stress



Logistics & Deliverables

- Date and Format:
 - Virtual Workshop
 - April 13-14, 2023
- Deliverables:
 - Workshop Summary Publication
 - Recommendations that may inform potential future NIDDK funding initiatives

Scientific Workshop on Expanding the Evidence Base in GENDER-AFFIRMING CARE for Transgender & Gender Diverse Populations

March 27, 2023 by webcast

https://videocast.nih.gov/

Rationale For Workshop

Despite becoming more visible in society, transgender persons suffer from substandard treatment within health care systems

Goal

Identify and prioritize key research needed to further the evidence base in gender-affirming care for transgender and gender diverse populations

Sponsors

Sexual & Gender Minority Research Office (SGMRO) 10 NIH ICOs, including NIDDK

Gender- Affirming Care and NIDDK Mission

- Effects of gender-affirming hormones on NIDDK organs and processes
 - oe.g. metabolism, diabetes, kidney, liver, GI tract, adipose tissue
- Surgical outcomes of gender affirming care, including genital surgery
- Impact of stigma and discrimination on NIDDK conditions

Scientific Workshop Agenda Highlights

Welcome: Admiral Rachel L. Levine, MD, Assistant Secretary for Health, Health and Human Services

Keynote Presentation: Overview of WPATH Standards of Care

Working Group Report back Sessions on Research Opportunities in:

- Pediatric and Adolescent Care
- Adult and Older Adult Care
- Systemic, Institutional, and Ethical Policies

Materials posted summer 2023 at https://dpcpsi.nih.gov/sgmro

Completed Meetings and Workshops



YET TO BE CHARTED:

Lymphatic System in Health and Disease

September 19-20, 2022





Patricia Greenwel, NIDDK Selen Catania, NHLBI Ilsa Rovira, NHLBI



Rationale for Workshop

- The lymphatic system is very complex and affects the function of most organs in the body. A better understanding of this system could lead to the development of novel therapies for conditions affecting lymphatics, including lymphedema, inflammatory bowel disease and obesity.
- The purpose of this 2-day workshop was to bring together basic, translational and clinical scientists who are interested in the role of the lymphatic system in health and disease to present the latest advances in the field, engage in interdisciplinary discussions and to identify knowledge gaps and opportunities in lymphatic disease research.

Organizing Committee

- Babak Mehrara, MD, Memorial Sloan Kettering Cancer Center
- Andrea Radtke, PhD, National Institute of Allergy and Infectious Diseases
- Gwendalyn Randolph, PhD, Washington University School of Medicine
- Patricia Greenwel, PhD, National Institute of Diabetes and Digestive and Kidney Diseases
- Selen Catania, PhD, National Heart, Lung and Blood Institute
- Ilsa Rovira, MS, National Heart, Lung and Blood Institute

Agenda

Keynote Topics

- Mechanisms of Lymphatic Contractile and Valve Dysfunction in Metabolic Syndrome
 Michael Davis, PhD, University of Missouri School of Medicine
- NIH Efforts to Facilitate Lymphatic Research and Current Knowledge in Lymphatic Mapping - Zorina Galis, PhD, NHLBI
- Finding a Drug for Lymphedema: From Bedside to Bench and Another Round Trip -Stanley Rockson, MD, Stanford University School of Medicine

Session 1: Lymphatics Development and Role in Homeostatic Function

Session 2: Lymphatics in Inflammation and Diseases of the Digestive System

Session 3: Lymphatic Dysfunction Diseases

Session 4: Lymphedema

Session 5: Community's Perspective: Living with Lymphatic Disease

Session 6: New Technologies in Lymphatic Imaging and Mapping

Session 7: Gaps, Opportunities, and Conclusions

Lymphatics in the Digestive System

- The Left-Right Asymmetric Pitx2 Gene Regulates Intestinal Muscular-lymphatic Morphogenesis and Protects against Fatty Liver Disease – Natasza Kurpios, PhD, Cornell University
- Maintenance of Lymphatic Vessels Prevents Lymph Leakage and Obesity - Nada Abumrad, PhD, Washington University School of Medicine in St. Louis
- Lymphatic Capillaries Act as a Signaling Hub in the Intestinal Stem Cell Niche - Rachel Niec, MD, Ph.D., The Rockefeller University
- Roles of Intestinal Lymphatic Drainage and Remodeling in Health and Inflammatory Bowel Disease - Rafael Czepielewski, PhD, Washington University School of Medicine in St. Louis
- The Lymphatic System in Chronic Liver Disease Yasuko Iwakiri, PhD, Yale School of Medicine

Workshop Summary

Attendance:

Over 700 registrants, including basic/translational scientists, clinicians, patients and patient advocates

Deliverables:

- Gaps and research opportunities in the field were identified
- An executive summary was published on the NIDDK and NHLBI websites
- A manuscript is in preparation for publication in JCI (Gaps and Opportunities in Lymphatic Research)

Housing and Obesity: Gaps, Opportunities, and Future Directions for Advancing Health Equity

Sponsors: National Institutes of Health, Centers for Disease Control and Prevention, and U.S. Department of Housing and Urban Development

November 14-15, 2022



Workshop Goals







- Accelerate research on the role of housing insecurity on behaviors and pathways underlying risk for obesityrelated health disparities across the lifespan
- Leverage existing and identify new opportunities for multi-sector research opportunities
- Encourage research partnerships and collaborations across sectors, communities, and stakeholders

Workshop Organizing Committee

- Co-chairs:
 - -Danya Keene, Ph.D., Yale University
 - -Craig Pollack, M.D., Johns Hopkins University
- NIH Staff: NIDDK, NHLBI, NCI, NICHD, NINR, NIMHD, NINR, and ODP
- HUD staff
- CDC staff

Trans-agency Health and Housing Working Group

Day 1: Background and Key Considerations

Session I: Overview and Background—Housing, Obesity, and Health Equity

Session II: History of Housing, Structural Racism, and the Current Housing Context

Session III: Early Career Investigator Presentation Sessions

Session IV: Introduction to Federal Housing
Assistance Programs and Research
Opportunities

Day 2: Focus on Interventions

Session A: Intervening on Housing and its Neighborhood Context

Session B: Housing Support and Stability Interventions

Session C: Delivering Evidence-Based Obesity Interventions in the Housing Context

Session D: Roles for Healthcare Systems

Breakout Listening Sessions

Workshop Summary

Attendance

 Over 800 registrants, including individuals from academia, housing authorities, healthcare systems, non-profits, and other stakeholder organizations

Deliverables

- Identification of key questions, novel research opportunities, and important partnerships
- Executive Summary (in progress) will be posted on NIDDK's website