



# Announcing The CPDD 2020 Scientific Meeting Virtual Experience

June 22-24, 2020

**MONDAY, JUNE 22, 2020**

**10:00 a.m. - 11:55 a.m.**

## **PLENARY PROGRAM & AWARDS PRESENTATION**

Elise Weerts, *Johns Hopkins University School of Medicine*

**Plenary Overview** This plenary serves as the opening session of the 2020 Annual meeting for CPDD. Dr. Weerts (Chair) will review the challenges and accomplishments of CPDD over the last year, provide an overview of the virtual meeting events, and announce award winners. Dr. Volkow (Speaker) will provide an update on NIH/NIDA funding priorities and feature research of interest. Dr. George Koob (speaker) will highlight the 50 years of progress of NIH/NIAAA research and provide an update on NIAAA funding priorities.

## **1.1 RESEARCH ON DRUG ABUSE AND ADDICTION: PROGRESS, OPPORTUNITIES AND CHALLENGES**

Nora Volkow, *National Institute of Drug Abuse, National Institutes of Health*

**Abstract:** Ongoing research on drug abuse and addiction has advanced our understanding of the nature and extent of these disorders in the US and globally and it has also advanced their prevention and treatment. Recent data from the annual NIDA-funded Monitoring the Future Study indicates that vaping of nicotine and/or marijuana is on the rise among young people. And despite new evidence of its potentially harmful effects on the user's brain and body, marijuana use is being recorded at historic highs among college-age adults. This country's opioid epidemic remains alarmingly high and the use of stimulant drugs like methamphetamine is, once again, showing a resurgence. In addition, some populations with substance abuse disorders are likely being particularly hard hit by the advent of the COVID-19 pandemic. Because it attacks the lungs, the coronavirus that causes COVID-19 could be an especially serious threat to those who smoke tobacco or marijuana or who vape. People with opioid use disorder (OUD) and methamphetamine use disorder may also be vulnerable due to those drugs' effects on respiratory and pulmonary health. This presentation will highlight current trends in the use of drugs of abuse, provide an update on the opioid epidemic, describe the disproportionate impact that the COVID-19 pandemic is having on some drug abusing populations, and describe relevant policy and research initiatives currently being supported by NIDA and the National Institutes of Health (NIH) to help address some of the most pressing challenges currently confronting the drug abuse and addiction field.

## **1.2 NIAAA: UPDATE STATE OF THE SCIENCE**

George Koob, *National Institute on Alcohol Abuse and Alcoholism*

**Abstract:** Alcohol use disorder (AUD) causes an enormous amount of human suffering, loss of productivity and cost to our medical care system and the nation's economy. Deaths due to AUD have increased steadily since 1999 and AUD contributes significantly to the deaths of despair in U. S. society. Advances in the science of alcohol use disorders can lead the way to better diagnosis, treatment, and prevention of this significant public health problem. Conceptualizing alcohol use disorder from a heuristic 3 stage framework has led to a focus on

withdrawal/negative affect stage, and how negative emotional states fuel the transition to addiction on alcohol. Understanding developmental trajectories provides fundamental knowledge of vulnerability to alcohol pathology across the lifespan. Using these heuristic frameworks, current challenges include medications development for the hyperkatifeia side of AUD, women and alcohol, older adults and alcohol, pain and alcohol, sleep, and alcohol, closing the treatment gap, and scientifically defining and studying recovery. Addressing such challenges will facilitate the implementation evidence-based treatment for AUD in primary care, mental health, and other health care settings.

**1:30 p.m. - 2:25 p.m.**

***SYMPOSIUM: NICOTINE USE IN YOUTH: INFORMING MORE EFFECTIVE PREVENTION AND TREATMENT***

Andrea Villanti, *University of Vermont*

**Summary Abstract:** Nicotine use among youth has increased over the past two years, with 2019 data suggesting that nearly 30% of high school students have used an e-cigarette in the past 30 days. This corresponds to rapid changes in the tobacco marketplace, including the introduction of novel nicotine products likely to deliver nicotine more efficiently to users. Concerns about nicotine use in youth relate to potential impacts of nicotine exposure on brain development, likelihood of developing nicotine dependence, and potential for transition to the most harmful tobacco products (i.e., cigarettes, cigars). More recently, emergent cases of vaping-related lung injury have raised questions about the acute impacts of e-cigarette use for young people as well. This symposium provides insight into current research on adolescent nicotine use across the spectrum of basic science, clinical, and public health, with four main goals: 1) to describe mechanisms of addiction in young people from neuroimaging studies; 2) to examine youth responses to nicotine in clinical lab studies; 3) to summarize recent patterns of nicotine use among youth and potential drivers of these patterns; and 4) to explore the effectiveness of a text message intervention for quitting vaping in youth and young adults. Data and synthesis presented in this symposium will provide a comprehensive view of the state of youth nicotine use in the U.S., as well as providing questions for further inquiry and recommendations for future prevention and treatment interventions, including policies.

**2.1 MECHANISMS OF ADDICTION IN YOUTH**

Hugh Garavan, *University of Vermont*

**2.2 THE IMPACT OF A NICOTINE REDUCTION POLICY ON YOUTH**

Rachel Cassidy, *Brown University*

**2.3 EPIDEMIOLOGY OF YOUTH NICOTINE USE**

Andrea Villanti, *University of Vermont*

**2.4 DIGITAL TREATMENT FOR NICOTINE USE: EARLY OUTCOMES AND NOVEL RESEARCH FINDINGS**

Michael Amato, *Truth Initiative*

**2:30 p.m. - 3:30 p.m.**

***WORKSHOP: NAVIGATING A CAREER IN ADDICTION SCIENCE***

Cecilia Bergeria, *Johns Hopkins University School of Medicine*

**Summary Abstract:** Much like addiction, the pathway toward a career in addiction science is not always linear. The overarching goal of this workshop is to provide members in training with diverse perspectives on a career in addiction science. The workshop will focus on navigating the following career stages: 1) pre-/post-doctoral, 2) early career faculty member, and 3) careers outside of academia. The fourth presentation will discuss NIDA funding mechanisms available at each career stage. Finally, the workshop will conclude in breakout groups led by each panelist to provide more personalized interaction and career advice. Each presentation will outline steps that can be taken to maximize career stage-specific experiences to increase competitiveness as a job applicant. Examples of topics that will be covered include: how to choose your mentors; striking a balance between executing your mentor's vision and growing as an independent scientist; how to narrow down an innovative and significant research question; publishing amidst other responsibilities; obtaining grant-writing experience; establishing your niche and conveying its importance to potential employers; collaborating and networking; deciding whether to teach; life-work balance; finding the NIH funding mechanisms that are most appropriate for you and how to begin writing your grant; and crucial to it all – time management strategies. Each talk will have a centered theme of the value of your mentoring team as you travel the path to independent investigator.

**3.1 NAVIGATING THE PRE-DOCTORAL STAGE**

Cho-Hee Shrader, *Miller School of Medicine, University of Miami*

**3.2 DRUG ABUSE RESEARCH AT A PRIMARILY UNDERGRADUATE INSTITUTION: BALANCING THE CLASSROOM AND LABORATORY**

Ryan Lacy, *Franklin and Marshall College*

**3.3 NAVIGATING THE EARLY CAREER STAGE AT A RESEARCH INSTITUTION**

Mariana Sanchez, *Florida International University*

**3.4 NAVIGATING SUBSTANCE USE DISORDER CAREERS OUTSIDE OF ACADEMIA**

Alexandra Duncan, *The Pew Charitable Trusts*

**5:00 p.m. - 5:55 p.m.**

***HUMAN FORUM: ENGAGING VULNERABLE POPULATIONS IN ADDICTION RESEARCH: ETHICAL DILEMMAS AND RECOMMENDATIONS***

Victoria Votaw, *University of New Mexico*

**Summary Abstract:** The College on Problems of Drug Dependence Human Research Committee presents a forum focusing on ethical conduct of addiction research with vulnerable populations. Vulnerable populations in research include disadvantaged subgroups that require additional considerations or protections due to barriers protecting their own interests. Examples of vulnerable populations include children, pregnant women, and justice-involved persons.

Notably, substance use and its associated consequences disproportionately impact these populations. It is therefore necessary to engage these populations in addiction research to ensure generalizability of findings, and to ultimately benefit these subgroups. However, stigma against these populations and inadequate knowledge of common ethical dilemmas have contributed to participants' general distrust of research and low research participation rates. This forum will focus on ethical situations that arise in research with vulnerable populations and provide recommendations to ethically engage these populations in research. Discussion content will include the following: risk-benefit analysis, common abuses (e.g., coercion, undue influence), IRB considerations, recruitment, informed consent, appropriate compensation, and data privacy. The talks will be bookended by an introduction and a robust discussion period moderated by the forum co-chairs. To appeal to a wide array of audience members, the panel includes human subjects researchers ranging in experiences and populations studied and with diverse interests within the addiction research field.

#### **4.1 ENGAGING VULNERABLE POPULATIONS IN ADDICTION RESEARCH: ETHICAL DILEMMAS AND RECOMMENDATIONS**

Michele Staton, *University of Kentucky, College of Medicine*

#### **4.2 ETHICS FOR TWO: ETHICAL CONSIDERATIONS FOR ENGAGING PREGNANT AND POSTPARTUM WOMEN WITH SUBSTANCE USE DISORDERS IN RESEARCH**

Hendree Jones, *University of North Carolina at Chapel Hill*

#### **4.3 "I DON'T LIKE A LOT OF PEOPLE KNOWING MY BUSINESS": ENGAGING YOUTH AND THEIR CAREGIVERS IN ADDICTION-TREATMENT RESEARCH**

Stacy Ryan-Pettes, *Baylor University*

#### **4.4 ETHICAL CONSIDERATIONS IN RESEARCH WITH JUSTICE-INVOLVED INDIVIDUALS**

Michele Staton, *University of Kentucky, College of Medicine*

#### **4.5 ETHICAL CONSIDERATIONS IN CONDUCTING RESEARCH WITH AMERICAN INDIAN/ALASKA NATIVE COMMUNITIES: OPPORTUNITIES FOR IMPACTFUL COLLABORATIONS AND RECOMMENDATIONS FOR ALLIES**

Kamilla Venner, *University of New Mexico*

#### **4.6 THE ETHICS OF INCLUSION AND REPRESENTATION: RESEARCH CONSIDERATIONS AMONG YOUTH AND SEXUAL AND GENDER MINORITY POPULATIONS**

Morgan Philbin, *Columbia University Mailman School of Public Health*

**6:00 p.m. - 6:55 p.m.**

#### **WORKSHOP: DEMYSTIFYING THE NIH PEER REVIEW PROCESS**

Miriam Mintzer, *CSR/NIH*

**Summary Abstract:** The National Institutes of Health (NIH) is the largest public funder of biomedical and biobehavioral research in the United States, including work presented at the CPDD Annual Scientific Meeting. This workshop will educate attendees about the peer review process for grant applications submitted to the NIH and will provide tips for successfully navigating the process from several different perspectives. Review staff from the Center for Scientific Review (CSR) at the NIH will present the nuts and bolts of the process from submission of the application to release of the summary statement after the review meeting. Program staff from the National Institute on Drug Abuse (NIDA) will describe the role of the NIH funding institutes in the process, including publishing Funding Opportunity Announcements and Notices of Special Interest, advising investigators on their submissions, and ultimately recommending applications for funding. An experienced reviewer who has served as a standing member of a chartered NIH scientific review group will describe the role of the reviewer in the process and provide insight into the factors that shape a reviewer's evaluation of an application. An ad hoc NIH reviewer who first participated as an Early Career Reviewer will talk about his review experiences and share lessons that have informed his own grant application submissions.

### **5.1 AN OVERVIEW OF THE NIH PEER REVIEW PROCESS**

Miriam Mintzer, *CSR/NIH*

### **5.2 THE NUTS AND BOLTS OF NIH PEER REVIEW**

Kristen Prentice, *Center for Scientific Review, National Institutes of Health*

### **5.3 NIH PROGRAM STAFF ROLE IN THE PEER REVIEW PROCESS**

Mary Kautz, *National Institute of Drug Abuse, National Institutes of Health*

### **5.4 AN EXPERIENCED REVIEWER'S PERSPECTIVE ON NIH PEER REVIEW**

William Stoops, *University of Kentucky*

### **5.5 AN EARLY CAREER REVIEWER'S PERSPECTIVE ON NIH PEER REVIEW**

Matthew Sutherland, *Florida International University*

**TUESDAY, JUNE 23, 2020**

**11:00 a.m. - 11:55 a.m.**

### ***WORKSHOP: CLINICAL USE OF CANNABINOIDS: POTENTIAL PROMISES AND PITFALLS***

Staci Gruber, *McLean Hospital, Harvard Medical School*

**Summary Abstract:** Cannabis has been used for medicinal purposes for thousands of years, yet many questions remain regarding the impact of its use on health outcomes. Access to cannabis is rapidly expanding and growing numbers of individuals use cannabis-based products to treat a variety of health conditions. This symposium will synthesize data from multiple studies that evaluated the impact of medicinal cannabinoid use on general health outcomes, cognition, behavior, drug testing, and risk for misuse. Specifically, Dr. Vandrey will

present data from a large, longitudinal survey-based study of patients with diverse health problems who self-report improvement following the use of medicinal cannabis compared to non-using control patients. Dr. Gruber will review data from a longitudinal observational study of medicinal cannabis patients, highlighting cognitive and clinical outcomes, the specific impact of THC vs CBD regimens, and the potential for abuse liability. Dr. Loflin will discuss the medicinal use of cannabis as it relates to drug testing, highlighting data from studies where participants have unexpectedly tested positive for THC, which raises potential concerns for consumers unaware of this possibility. Finally, Dr. McGregor will overview results from recent surveys, clinical trials and laboratory studies in Australia examining population use of cannabis for medical conditions, efficacy of CBD and THC products in treating anxiety disorders and addictions, and the detection of driving impairment. Dr. Cooper will synthesize findings from these studies and discuss results from randomized controlled trials of cannabis-based products, highlighting the need for more work in this area.

### **6.1 SELF-REPORTED HEALTH OF MEDICINAL CANNABIS USERS VERSUS CONTROLS: RESULTS FROM A LONGITUDINAL SURVEY STUDY**

Ryan Vandrey, *Johns Hopkins University School of Medicine*

### **6.2 DIRECT EXAMINATION OF MEDICAL CANNABIS PATIENTS: COGNITIVE AND CLINICAL OUTCOMES, THC VS. CBD REGIMENS, AND POTENTIAL ABUSE LIABILITY**

Staci Gruber, *McLean Hospital, Harvard Medical School*

### **6.3 CBD AND COMMERCIAL DRUG TESTING FOR THC: UNEXPECTED RESULTS FROM ONGOING CBD TRIALS**

Mallory Loflin, *University of California - San Diego, School of Medicine*

### **6.4 CANNABIS EFFECTS ON ANXIETY, ADDICTIONS AND DRIVING: RECENT RESEARCH FROM AUSTRALIA**

Iain McGregor, *The University of Sydney*

**11:00 a.m. - 11:55 a.m.**

### ***SYMPOSIUM: THE RESURGENCE OF ILLICIT STIMULANTS IN THE ONGOING SUBSTANCE USE DISORDER EPIDEMIC***

William Stoops, *University of Kentucky*

**Summary Abstract:** Epidemiological estimates indicate that illicit stimulant use is increasing. For example, NSDUH data suggest that the number of Americans reporting current use of cocaine or methamphetamine was higher in 2017 than in 2016. Significant increases in overdose from cocaine and methamphetamine were also observed from 2011 through 2016. There is a growing recognition of the morbidity and mortality posed by illicit stimulant use, either through the noted increases in drug overdose or through health problems caused by chronic stimulant intake. This problem is made even more urgent given that there is a lack of standardized treatment protocols or approved pharmacotherapies to address stimulant use. This symposium will feature presenters who will provide insights into the current cycle of resurgent illicit stimulant use, including epidemiology (Matthew Ellis), available treatment options

(Kathleen Carroll) and clinical and preclinical medications development efforts (Frances Levin and Chang-Guo Zhan, respectively). William Stoops will then briefly synthesize these presentations, after which he will moderate a discussion between panel and audience members, focusing on the opportunities and challenges posed by current approaches to addressing illicit stimulant use. This session consists of presentations that cover a translational spectrum and uses an interactive format that combines data presentations with audience/panel discussion to identify and target new and important directions for research in our efforts to address stimulant use disorder.

### **7.1 RECENT INCREASES IN ILLICIT STIMULANT USE IN THE UNITED STATES: EPIDEMIOLOGY, DRIVING FORCES AND POLYSUBSTANCE USE**

Matthew Ellis, *Washington University*

### **7.2 UPDATE ON TREATMENT OF STIMULANT USE DISORDER**

Kathleen Carroll, *Yale University School of Medicine*

### **7.3 CLINICAL DEVELOPMENT OF PHARMACOTHERAPIES FOR FUTURE TREATMENT OF COCAINE AND METHAMPHETAMINE USE DISORDERS**

Frances Levin, *Columbia University Irving Medical Center/ New York State Psychiatric Institute*

### **7.4 PRECLINICAL DEVELOPMENT OF PHARMACOTHERAPIES FOR FUTURE TREATMENT OF COCAINE AND METHAMPHETAMINE USE DISORDERS**

Chang-Guo Zhan, *University of Kentucky*

**12:00 p.m. - 12:55 p.m.**

### ***PRESIDENTIAL SYMPOSIUM: A TRANSLATIONAL DISCUSSION OF THE THERAPEUTIC POTENTIAL AND ADVERSE CONSEQUENCES OF CANNABINOIDS***

*Elise Weerts, Johns Hopkins University School of Medicine*

**Plenary Overview:** Changes in federal legislation to remove hemp from the controlled substances act and state regulation of cannabis for medical and non-medical purposes have resulted in proliferation of products containing the phytocannabinoids  $\Delta^9$ -tetrahydrocannabinol (THC) and cannabidiol (CBD). This symposium brings together leading translational researchers in the cannabinoid field to discuss the potential medical benefits, abuse liability and adverse consequences of cannabis, THC and CBD use. Dr. Michael Taffe will describe preclinical research in which he examines the interactive effects of CBD with THC with a focus on different outcomes between non-human primate and rodent investigations. Vapor inhalation in rats as a model of human cannabis smoking and vaping will be discussed with a focus on the differences compared with traditional injection routes of administration. Dr. Yasmin Hurd will discuss results from preclinical animal models and human studies that assess the effects of developmental cannabis/THC exposure as well as translational animal and human studies evaluating the potential therapeutic effects of CBD for anxiety and addiction. Dr. Ziva Cooper will discuss the use of cannabis constituents THC and CBD as potential therapeutics in decreasing or eliminating opioid use for pain management.

She will describe findings from controlled human laboratory studies probing these phytocannabinoids as novel opioid-sparing pharmacotherapeutic strategies.

### **8.1 MODELING THE EFFECTS OF THC AND CANNABIDIOL IN RODENTS AND NON-HUMAN PRIMATES**

Michael Taffe, *University of California, San Diego*

**Abstract:** The use of cannabinoid compounds  $\Delta$ 9-tetrahydrocannabinol (THC) and cannabidiol (CBD) for medicinal and recreational purposes continues to expand, as legal barriers are dismantled. Understanding of the effects of CBD by itself, and in combination with THC, are only recently being explored in well-controlled studies. This talk will discuss the interactive effects of CBD with THC in animal models with a focus on different outcomes between non-human primate studies and rat investigations. Most pre-clinical models of cannabinoid effects use parenteral injections of cannabinoids, while human use continues to be by inhalation via combusted plant material and, now, e-cigarette devices. Models of vapor inhalation in rats will be discussed with a focus on the differences compared with traditional injection routes of administration.

### **8.2 TRANSLATING CANNABIS: NEUROBIOLOGICAL INSIGHTS TO RISKS AND THERAPEUTIC POTENTIAL**

Yasmin Hurd, *Icahn School of Medicine at Mount Sinai*

**Abstract:** The sociopolitical landscape has dramatically changed over the past few years regarding the recreational and medicinal use of cannabis. Federal and state policies have evolved in large part devoid of scientific input, but more attention is being given to incorporating knowledge gained from basic science and clinical research to guide new and existing policies. An important issue relates to the developmental effects of cannabis given the sensitivity of the developing brain — fetal, childhood and adolescence— to adverse environmental conditions that places individuals at risk for addiction and related psychiatric disorders later in life. Translational studies from basic molecular and behavioral animal studies to human longitudinal investigations strongly suggest long-term impact of prenatal cannabis/THC on synaptic plasticity and behavioral disturbances especially in line with anxiety/stress and addiction vulnerability. While THC has been linked to many of the negative outcomes associated with cannabis, recent attention has also focused on another cannabinoid, cannabidiol (CBD). Translational approaches suggest that CBD reduces anxiety and recent clinical trials provide evidence that CBD attenuates cue-induced craving and anxiety relevant to opioid addiction. There, however, remain many unknown and discrepancies in the field about THC and CBD relevant to the potential risks and benefits of cannabinoids. Insights gained from animal and clinical studies provide a translational foundation to guide interpretation of data accumulated to date and provide a framework on topics of focus for the future as we move into a new era of cannabis/cannabinoid research.

### **8.3 CANNABIS CONSTITUENTS AND THE OPIOID EPIDEMIC: PROMISE OR PLIGHT?**

Ziva Cooper, *UCLA Cannabis Research Initiative*

**Abstract:** Opioids are a primary contributing factor in substance related overdose deaths. Cannabis constituents, such as the phytocannabinoids delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) may have a role in decreasing or eliminating opioid use for pain



management. This presentation will highlight controlled human laboratory studies probing these phytocannabinoids as novel opioid-sparing pharmacotherapeutic strategies.

**1:30 p.m. - 2:00 p.m.**

**MINI-SYMPOSIUM: USE OF DRUGS BY PARENTS AND THEIR OFFSPRING**

*Wilson Compton, National Institute of Drug Abuse, National Institutes of Health*

**Summary Abstract:** The health consequences of early drug initiation is a growing concern. Peer influence, genetics, family environment, family interactions, and quality of parenting are among the many risk and protective factors influencing the use of drugs among offspring. With peak use of drugs among adults of child-bearing and child-rearing ages, parents using drugs conceivably pose a direct environmental risk of normalizing drug use and enabling access for their offspring. Reportedly, if both parents and peers use marijuana, youth use is highest compared with non-using counterparts, whereas peer influence on children's drug use can be neutralized by parents who do not use substances. Intergenerational transmission of drug use is a compelling cause of concern, as living with a parent using substances or harboring a substance use disorder is an explicit risk for use of substances among young people. To address these issues, this mini-symposium will examine the associations between parental substance use and offspring use of marijuana and other drugs. We will examine potential intergenerational associations both within specific substances and across substances. This mini-symposium can inform clinicians, parents, and policy-makers on substance use prevention.

**9.1 TRENDS IN CANNABIS AND CIGARETTE USE AMONG ADULTS WITH CHILDREN IN THE HOME: THE ROLE OF DEPRESSION**

*Renee Goodwin, The City University of New York*

**9.2 E-CIGARETTE USE IS RELATED TO LATER CIGARETTE USE IN YOUNG ADULTHOOD, OVER AND ABOVE ANTECEDENT RISK FACTORS: A PROPENSITY SCORE ANALYSIS**

*Marina Epstein, University of Washington*

**9.3 CANNABIS USE BY PARENTS LIVING WITH ADOLESCENT AND YOUNG ADULT OFFSPRING: NATIONAL SURVEY ON DRUG USE AND HEALTH RESULTS**

*Wilson Compton, National Institute of Drug Abuse, National Institutes of Health*

**1:30 p.m. - 2:00 p.m.**

**MINI-SYMPOSIUM: IMMUNOLOGICAL APPROACHES TO THE FENTANYL EPIDEMIC**

*Marco Pravetoni, University of Minnesota Medical School*

**Summary Abstract:** Our GOAL is presenting new immunotherapeutic approaches to reduce fentanyl abuse and to prevent fentanyl overdose with vaccines and monoclonal antibodies (mAB). The SIGNIFICANCE is that fentanyl can easily over-ride the competitive blockade of methadone, buprenorphine and naltrexone, and that fentanyl overdose is not typically reversed after standard intranasal naloxone dosing. Thus, more effective strategies are needed

to prevent misuse, relapse and fentanyl overdoses related to fentanyl street mixtures. Session I will cover an opiate vaccine that is ready for clinical trials and may last up to 6 months after full vaccination. Session II will cover anti-fentanyl vaccines currently being developed in rodent models and will discuss their antibody response as well as their ability to block analgesia and respiratory depression from fentanyl. Session II will also cover lessons learned from clinical studies over the past 25 years with an anti-cocaine vaccine that has been the model for the current anti-fentanyl vaccines. One lesson learned is that inadequate antibody responses to these vaccines for blocking the abused drug occurs in up to one-third of humans vaccinated. New vaccine adjuvants are being explored for this problem. Session III will focus on development of both vaccines and mAb to counteract fentanyl as well as biomarkers predictive of individual variability in vaccine efficacy against fentanyl and other opioids. For instance, mAb may be deployed to counteract acute fentanyl-induced toxicity and overdose in emergency setting and potentially be combined to naloxone to improve survival after accidental or deliberate exposure to fentanyl and its analogs.

### **10.1 LONG-ACTING OPIOID VACCINE**

Gary Matyas, *Walter Reed Army Institute of Research*

### **10.2 FENTANYL IMMUNOTHERAPY AND MONOCLONAL ANTIBODIES**

Marco Pravetoni, *University of Minnesota Medical School*

**2:00 p.m. - 2:55 p.m.**

#### ***SYMPOSIUM: AGING AND ADDICTION: PROMOTING CROSSTALK BETWEEN TWO FIELDS OF RESEARCH***

Cassandra Gipson-Reichardt, *University of Kentucky*

**Summary Abstract:** Drugs of abuse may contribute to accelerated aging and age-related illness. Few studies have examined neurobehavioral mechanisms of addiction while considering aging as a biological variable. Thus, there is a large gap between two fields which could contribute to slowed progress in treating both substance use disorders (SUDs) as well as age-related diseases. The studies that comprise this panel highlight potential overlapping mechanisms, which may lend insight into how drugs of abuse alter the trajectory of aging. First, this panel will demonstrate that the proportion of older adults seeking treatment for SUDs has increased in recent years. Subsequently, we will describe the relationship between smoking and factors unique to women's reproductive health during transitional menopause. To follow, this panel will describe interactions between amyloid peptides and nicotinic acetylcholine receptors (nAChRs), and how this can alter neural stability and contribute to cognitive decline associated with aging (specifically, Alzheimer's Disease).  $\alpha 4\beta 2$ \*nAChRs have been shown to play a critical role in drug use and related anxiety phenotype. This panel will show that a decline of  $\alpha 4\beta 2$ \*nAChR expression during aging supports changes in anxiety-like behavior and intracellular signaling with age-dependent effects of selective pharmacological manipulation of these receptors to suggest that an aging population may not only respond differently to nicotine and withdrawal, but also to pharmacotherapies for tobacco cessation. In summary, this translational panel will present data highlighting overlapping mechanisms of addiction and aging in order to promote crosstalk between two fields and address medical complexities of older adults with SUDs.

### **11.1 TRENDS IN OLDER ADULTS SEEKING TREATMENT FOR SUBSTANCE USE DISORDERS**

Andrew Huhn, *Johns Hopkins University School of Medicine*

### **11.2 MENOPAUSE, NICOTINE DEPENDENCE, AND SMOKING CESSATION**

Amy Copeland, *Louisiana State University*

### **11.3 THE ROLE OF NICOTINIC ACETYLCHOLINE RECEPTORS IN AMYLOID-INDUCED ALTERATIONS IN NEURONAL AND NETWORK-LEVEL EXCITABILITY**

Andrew George, *The Barrow Neurological Institute*

### **11.4 ALPHA4BETA2 NICOTINIC ACETYLCHOLINE RECEPTOR EXPRESSION IMPACTS ANXIETY-LIKE PHENOTYPE DURING AGING**

Darlene Brunzell, *Virginia Commonwealth University*

**2:00 p.m. - 2:55 p.m.**

#### ***WORKSHOP: DIGITAL DELIVERY OF FUTURE THINKING INTERVENTIONS TO REDUCE TEMPORAL DISCOUNTING AND SUBSTANCE USE***

Michael Sofis, *Geisel School of Medicine at Dartmouth*

**Summary Abstract:** Excessive devaluation of delayed rewards, i.e., delay discounting (DD), is an important explanatory mechanism that contributes to substance use disorders (SUDs) and represents a promising therapeutic target for reducing substance use. Brief interventions that shift attention toward future events may lessen overvaluation of immediate substance-related reinforcers and increase preference for larger, later rewards. Two interventions, Episodic Future Thinking (EFT), prospective simulation of positive and personally relevant future events, and Future Thinking Priming (FTP), which nudges temporal attention towards future events, have produced positive effects on DD and substance use. This symposium will highlight potential efficacy of brief, online future thinking interventions to reduce DD and substance use relative to recent-focused control conditions across multiple substances. Dr. Sheffer will present a study that showed reductions in DD two weeks following an FTP session in a large, non-clinical adult sample. Dr. Snider will highlight positive effects of EFT on DD compared to a recent thinking control in those recovering from SUDs. Dr. Sofis' findings will illustrate how an online EFT session that prompts future thinking in specific life domains reduces DD and cannabis use compared to a recent thinking control at one-week follow-up. Dr. Bickel will illustrate the impact of EFT on reinforcer pathology (DD and demand) using findings from controlled studies and a field trial demonstrating reduced alcohol consumption after EFT relative to control. The discussant, Dr. Iguchi, will synthesize these findings to comment on the potential for these brief interventions to reduce substance use as independent or adjunctive interventions.

### **12.1 A WEB-BASED EPISODIC SPECIFICITY AND FUTURE THINKING SESSION MODULATES DELAY DISCOUNTING IN CANNABIS USERS**

Michael Sofis, *Geisel School of Medicine at Dartmouth*

## **12.2 EPISODIC FUTURE THINKING AMONG INDIVIDUALS IN RECOVERY FROM SUBSTANCE USE DISORDER**

Sarah Snider, *Fralin Biomedical Research Institute at VTC*

## **12.3 PRIMED FOR HEALTH? DECREASING DELAY DISCOUNTING WITH FUTURE THINKING PRIMING**

Christine Sheffer, *Roswell Park Comprehensive Cancer Center*

## **12.4 REPAIRING REINFORCER PATHOLOGY WITH EPISODIC FUTURE THINKING: FROM LAB TO CLINIC**

Warren Bickel, *Fralin Biomedical Research Institute at VTC*

**5:00 p.m. - 5:55 p.m.**

### ***ANIMAL FORUM: GAINING PERSPECTIVE ON NONHUMAN ANIMAL MODELS OF SUBSTANCE USE DISORDERS: INSIGHTS FROM NIDA'S RECENT RFI***

Mark Smith, *Davidson College*

**Summary Abstract:** Representatives from the National Institute on Drug Abuse (NIDA) will provide information learned from the Request for Information (RFI) concerning Nonhuman Animal Models of Substance Use

## **13.1 GAINING PERSPECTIVE ON NONHUMAN ANIMAL MODELS OF SUBSTANCE USE DISORDERS: INSIGHTS FROM NIDA'S RECENT RFI**

Jennifer Wenzel, *NIH/NIDA*

## **13.2 GAINING PERSPECTIVE ON NONHUMAN ANIMAL MODELS OF SUBSTANCE USE DISORDERS**

Holly Moore, *NIDA (E)*

**6:00 p.m. - 6:55 p.m.**

### ***POLICY FORUM: ANNUAL UPDATE FROM CAPITOL HILL AND A PANEL ON ADVANCES IN HALLUCINOGEN RESEARCH***

Martin Iguchi, *RAND Corporation*

**Summary Abstract:** The Policy Forum (now in its 14th year) will consist of two parts. In Part I brief remarks summarizing Friends of NIDA's activities and accomplishments in the past year will be followed by an overview/report from Capitol Hill on budgetary and other factors affecting substance abuse research.

Part II will be a panel discussing the rapidly advancing research on hallucinogens, with a discussion of implications for treatment, barriers to research in novel domains examining previously stigmatized drugs, and implications for policy/regulatory actions as some communities begin to decriminalize the drugs (e.g. Oakland, Denver).

#### **14.1 POLICY FORUM: ANNUAL UPDATE FROM CAPITOL HILL AND A PANEL ON ADVANCES IN HALLUCINOGEN RESEARCH**

Edward Long, *Van Scoyoc Associates*

#### **14.2 RECENT ADVANCEMENTS IN RESEARCH WITH PSILOCYBIN AND IMPLICATIONS FOR TREATMENT**

Matthew Johnson, *Johns Hopkins University School of Medicine*

#### **14.3 TBD**

Peter Hendricks, *University of Alabama*

#### **14.4 CONSIDERING THE LIBERALIZATION OF PSYCHEDELIC DRUG LAWS: POLICY UPDATE AND DESIGN CHOICES**

Bryce Pardo, *RAND Drug Policy Research Center*

**6:00 p.m. - 6:55 p.m.**

#### ***WORKSHOP: MISSING DATA MATTERS: SUBSTANCE USE DISORDER TRIALS***

Aimee Campbell, *Columbia University and New York Psychiatric Institute*

**Summary Abstract:** Clinical trials with individuals who have substance use disorders are known to suffer from high rates of missing longitudinal outcome data. In the presence of missing data, inference about treatment effects must rely on untestable assumptions, which inaccurately stated can lead to incorrect conclusions. This workshop will present clinically-informed information on assumptions about missing data, describe standard statistical methods for managing missing data, and demonstrate a novel global sensitivity analysis procedure recently developed with funding from NIDA. Dr. Nunes (Columbia University) will present the clinical challenges and assumptions associated with missing data in substance use disorder trials (15 minutes). Dr. Matthews (The EMMES Company) will survey the primary analytic strategies of trials conducted through NIDA's Clinical Trials Network (CTN) (20 minutes). Dr. Pavlicova (Columbia University) will discuss analytic strategies employed in secondary and exploratory analyses of data from specific CTN and other substance use disorder trials (15 minutes). Dr. Scharfstein (Johns Hopkins University) will introduce a global sensitivity analysis methodology developed to rigorously evaluate the robustness of clinical trial results to missing data assumptions; he will demonstrate the methodology in the context of a CTN trial designed to evaluate the effectiveness of a digital therapeutic to reduce substance use among patients in outpatient addiction treatment (40 minutes). Dr. Feaster (University of Miami) will serve as the discussant and facilitate Q&A (30 minutes). Workshop attendees will obtain a greater understanding of how to conceptualize missing data assumptions and a range of analytic methods for addressing missing data in their own trials.

#### **15.1 THREATS TO THE VALIDITY OF CLINICAL TRIALS DUE TO DIFFERENTIAL ATTRITION: CLINICAL CONSIDERATIONS**

Edward Nunes, *Columbia University and New York State Psychiatric Institute*

## **15.2 MISSING DATA IN THE CTN**

Abigail Matthews, *The Emmes Company*

## **15.3 MISSING DATA: ANALYTIC STRATEGIES IN SECONDARY AND EXPLORATORY ANALYSES**

Martina Pavlicova, *Columbia University*

## **15.4 GLOBAL SENSITIVITY ANALYSIS OF RANDOMIZED TRIALS WITH NON-MONOTONE MISSING BINARY OUTCOMES: APPLICATION TO STUDIES OF SUBSTANCE USE DISORDERS**

Daniel Scharfstein, *Johns Hopkins Bloomberg School of Public Health*

**7:00 p.m. - 7:55 p.m.**

### ***WORKSHOP: DESIGN AND ANALYSIS WORKSHOP***

Sterling McPherson, *Washington State University Elson S. Floyd College of Medicine*

**Summary Abstract:** In this fifth Annual CPDD Design and Analysis Workshop, the primary goal remains exposing attendees to state-of-the-art analytic methods relevant to substance use research. This year's workshop introduces Bayes statistical approaches and provides real-world examples as well as notable cautions of their use in practice. Our specific aims address the following topics: 1) an introduction to Bayesian statistics and how to implement with commercially available software; 2) latent class modeling for predicting a distal outcome and identifying unique profiles of cannabis and tobacco co-use; 3) predictive growth mixture models for opioid treatment relapse using Clinical Trials Network data; 4) cautions in using empirical Bayes predictors from mixed models, and 5) leveraging multilevel models to understand the nature of substance abuse correlates. Each of these topics is timely and important for multiple domains of substance use research. Some are general while some focus on the analysis of treatment data and others are best suited to observational data. All presentations will be in a non-technical, accessible fashion in an effort to generate discussion among presenters and audience members around considerations such as: applicability of the methods to various situations, potential limitations, resources for additional information, and future directions. As in the prior Design and Analysis Workshops, our intent is to empower other researchers by disseminating state-of-the-art methods as applied to real-world examples. The overall goal is to raise awareness and the level of quality in the methods that prevail throughout substance use research

## **16.1 AN INTRODUCTION TO BAYESIAN STATISTICS**

Sterling McPherson, *Washington State University Elson S. Floyd College of Medicine*

## **16.2 USING MIXTURES TO PREDICT A LATENT SURVIVAL OUTCOME**

Noel Vest, *Stanford University School of Medicine*

## **16.3 PREDICTING A DISTAL OUTCOME WITH UNIQUE PROFILES OF CANNABIS AND TOBACCO ADOLESCENT CO-USERS**

Crystal Smith, *Washington State University*

## **16.4 CAUTIONS IN USING EMPIRICAL BAYES PREDICTORS: SURPRISING ASSUMPTIONS UNDERLYING SUBJECT-SPECIFIC ESTIMATES FROM MIXED MODELS**

Susan Mikulich-Gilbertson, *University of Colorado School of Medicine*

## **16.5 LEVERAGING MULTILEVEL MODELS TO UNDERSTAND THE NATURE OF SUBSTANCE ABUSE CORRELATES**

Jarrold Ellingson, *University of Colorado Anschutz Medical Campus*

**7:00 p.m. - 7:55 p.m.**

### ***WORKSHOP: COMMUNITY ENGAGEMENT STRATEGIES FOR ADDRESSING SUBSTANCE USE IN RACIAL/ETHNIC COMMUNITIES***

A. Kathleen Burlew, *University of Cincinnati*

**Summary Abstract:** Growing evidence shows that intervention research grounded in community knowledge while including community members as partners has greater potential to improve community health outcomes. Community engagement may be even more important for addressing substance use in racial/ethnic communities because the generic interventions may not fully address the needs of these communities. Nevertheless, guidance on collaborating effectively with community representatives to address substance use treatment is limited. The aim of this workshop is to share several models for conducting community engaged studies that have emerged in research conducted on racial/ethnic minorities within the NIDA Drug Abuse Treatment Clinical Trials Network (CTN). Dr. Danni Lanaway will discuss the evolution of a community engaged approach to cultural adaptation. Dr. Caravella McCuistian will provide information about a community/academic partnership aimed at reducing transactional sex among substance using women. Dr. Morgan Medlock will share insights from a Washington DC-based community advisory board on strategies for engaging African American communities in discussions about opioid use and medication-assisted treatment. Her presentation will include initial findings on barriers and facilitators of treatment engagement as well as steps taken to empower community leaders to participate in treatment innovation. Dr. Kamila Venner will discuss models of cultural tailoring versus cultural centering of evidence-based treatments with illustrations of adaptations as well as obstacles encountered in this community engaged work.

Following the presentations, Dr. LaTrice Montgomery will serve as a discussant and encourage the audience to share other models for community engagement.

## **17.1 THE EVOLUTION OF AN APPROACH FOR COMMUNITY ENGAGED CULTURAL ADAPTATION**

Danni Lanaway, *Atlanta VAMC/Emory University School of Medicine*

## **17.2 COMMUNITY COLLABORATION ADDRESSING TRANSACTIONAL SEX AND HIV PREVENTION AMONG SUBSTANCE USING WOMEN**

Caravella McCuistian, *University of California, San Francisco*

**17.3 WHAT DO WE KNOW ABOUT OPIOID USE IN THE BLACK COMMUNITY?  
AN APPRAISAL OF THE LITERATURE OVER THE PAST 20 YEARS**

Ayana Jordan, *Yale University School of Medicine*

**17.4 CULTURALLY TAILORING VERSUS CULTURAL CENTERING OF  
EVIDENCE-BASED TREATMENT IN PARTNERSHIP WITH UNDER-SERVED  
COMMUNITIES**

Kamilla Venner, *University of New Mexico*

**WEDNESDAY, JUNE 24, 2020**

**11:00 a.m. - 11:55 a.m.**

***SYMPOSIUM: ESTROGEN-CANNABINOID INTERACTIONS BOTH IN  
PRECLINICAL AND CLINICAL RESEARCH***

Elisa Pabon, *The University of Chicago, Department of Psychiatry*

**Summary Abstract:** There is increasing evidence in rodents and humans that the effects of cannabinoid drugs are sex-dependent, and that some of these differences are related to estrogen. This symposium will present recent research on estrogen-cannabinoid interactions and in both preclinical and clinical models. The session will begin by introducing the topic of sex differences in cannabinoid-regulated biological processes. Preclinical work investigating sex differences in how cannabinoids increase appetite, alter metabolism, and decrease excitatory neurotransmission within the hypothalamic energy balance circuitry will be presented. Next, the session will transition to estrogen-cannabinoid interactions in learning and memory in rats, and the development of tolerance to the exogenous cannabinoid,  $\Delta$ 9-tetrahydrocannabinol. To provide a translational application of estrogen-cannabinoid interactions, a clinical perspective will be presented investigating sex-dependent effects of cannabis in daily cannabis smokers. Finally, new data demonstrating interactions between circulating estradiol levels and responses to acute  $\Delta$ 9-tetrahydrocannabinol in healthy women will be presented. The symposium will conclude with a summary of ongoing work as well as stimulating a discussion regarding the future of estrogen-cannabinoid interactions. By delving deeper into estrogen-cannabinoid interactions, a foundation can be laid for sex-specific drug use guidelines, allowing for safer use of cannabis.

**18.1 ESTRADIOL ATTENUATES THE CANNABINOID REGULATION OF  
HYPOTHALAMIC ENERGY BALANCE CIRCUITS**

Edward Wagner, *Western University of Health Sciences*

**18.2 ESTROGEN-CANNABINOID INTERACTIONS ON LEARNING AND MEMORY  
IN RATS AND THE DEVELOPMENT OF TOLERANCE TO DELTA-9-  
TETRAHYDROCANNABINOL**

Peter Winsauer, *LSU Health Sciences Center School of Medicine*



### **18.3 IMPACT OF SEX AND ESTROGEN ON CANNABIS EFFECTS: TRANSLATING PRECLINICAL SCIENCE TO CLINICAL STUDIES**

Ziva Cooper, *UCLA Cannabis Research Initiative*

### **18.4 ACUTE RESPONSE TO ORAL DELTA-9-TETRAHYDROCANNABINOL IN RELATION TO MENSTRUAL CYCLE PHASE AND CIRCULATING ESTRADIOL**

Elisa Pabon, *The University of Chicago, Department of Psychiatry*

**11:00 a.m. - 11:55 a.m.**

### ***SYMPOSIUM: INNOVATIVE SOLUTIONS TO EXPAND TREATMENT FOR OPIOID USE DISORDER IN RURAL COMMUNITIES***

*Yih-Ing Hser, UCLA Integrated Substance Abuse Programs*

**Summary Abstract:** Dramatic increases in opioid use disorder (OUD) and opioid overdose deaths across the U.S. and other nations, particularly in rural areas, call for a rapid expansion of access to medication treatment for opioid use disorder (MOUD) in order to effectively address this public health crisis. Office-based opioid treatment (OBOT) is the prevailing standard of care for OUD treatment in primary care settings, but uptake of OBOT in rural areas has been slow, with significant shortages of buprenorphine prescribers in rural counties. This symposium will address emerging innovative approaches to OUD treatment, including telemedicine-based and pharmacy-based models, and integrated MOUD with HIV/HCV treatment to address unique barriers faced in rural communities. The aims of the symposium are to:

1. Describe telemedicine-delivered OUD treatment of veterans in rural areas and utilization and effectiveness of telemedicine-delivered treatment for veterans with OUD in the U.S. Veterans Health Administration.
2. Describe international models of care that have engaged pharmacists to increase the reach of medication treatment for OUD (MOUD), including efforts to develop and demonstrate a Prescriber/Pharmacist collaborative shared-care model of MOUD delivery in Australia.
3. Discuss integration and sustainability of office based opioid treatment (OBOT) with telemedicine (TM) within a NIDA Clinical Trials Network study focused on expansion of OUD treatment in rural primary care clinics across the U.S.
4. Describe strategies for providing integrated care for OUD and the infectious sequelae (HIV, HCV) of injection opioid use in rural settings.

### **19.1 TELEMEDICINE-DELIVERED TREATMENT FOR OPIOID USE DISORDER AMONG VETERANS**

Lewei (Allison) Lin, *University of Michigan*

### **19.2 ENHANCING ACCESS TO MEDICATION TREATMENT FOR OPIOID USE DISORDER (MOUD) THROUGH EXTENDED ROLES FOR PHARMACISTS**

Suzanne Nielsen, *Monash University*

### **19.3 RURAL EXPANSION OF MEDICATION TREATMENT FOR OPIOID USE DISORDER IN PRIMARY CARE SETTINGS**

Yih-Ing Hser, *UCLA Integrated Substance Abuse Programs*

### **19.4 INTEGRATING CARE FOR OPIOID USE DISORDER AND INFECTIOUS DISEASES IN RURAL WEST VIRGINIA**

Judith Feinberg, *West Virginia University School of Medicine*

**12:00 p.m. - 12:55 p.m.**

#### ***SYMPOSIUM: ADVANCING POLYSUBSTANCE RESEARCH WITH TRANSLATIONAL APPROACH***

Heather Kimmel, *National Institute of Drug Abuse, National Institutes of Health*

**Summary Abstract:** The funding opportunity “Integrative Research on Polysubstance Abuse and Addiction,” is supported by Collaborative Research on Addiction at the National Institutes of Health (NIH), a trans-NIH partnership composed of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Cancer Institute. The intent is two-fold: (1) characterize how the neurobiological alterations, associated behaviors, and public health consequences arising from polysubstance use differ from, or are similar to, those observed in single drug use; (2) promote integrative polysubstance research along a translational pipeline, consisting of basic science research in animals, human-based laboratory investigations, and epidemiological studies. These dual objectives are accomplished with a Phased Innovation (R21/R33) mechanism, where polysubstance research can occur in any translational stage during the R21 phase and these findings are rapidly integrated into another stage during the R33 phase, allowing for bi-directional research exchange. Six projects have been funded. In this symposium, awardees will discuss their research findings as well as how this mechanism facilitated their research. This program is unique in addressing the reality of polysubstance use as well as the challenges in conducting rigorous research in this area. In addition, the translational component deliberately brings together researchers from different fields to facilitate communication and understanding between the disciplines to address important public health questions. We will also provide program updates and recommendations to potential applicants. We will facilitate a discussion to identify specific research interests based on current events as well as mechanisms to help forge new collaborations.

### **20.1 PREEXISTING INHIBITORY CONTROL DEFICITS PREDICT COMPULSIVE DRUG USE IN AN ANIMAL MODEL OF HARM AVOIDANCE**

Kathleen Kantak, *Boston University*

### **20.2 NOVEL TOOLS AND MODELS TO STUDY THE PATTERNS AND CONSEQUENCES OF POLYSUBSTANCE USE IN HUMANS AND RODENTS**

Lori Knackstedt, *University of Florida*

### **20.3 INTEGRATIVE GENOMIC ANALYSIS OF HIDDEN PHENOTYPES ACROSS POLYSUBSTANCE USE DISORDERS**

Gita Pathak, *VA Connecticut Healthcare, Yale Medical School*

## **20.4 OPIOIDS AND BENZODIAZEPINES POLYDRUG ABUSE**

Cynthia Arfken, *Wayne State University*

**12:00 p.m. - 12:55 p.m.**

### ***SYMPOSIUM: FMRI DRUG CUE REACTIVITY (FDCR) AS A DRUG DEVELOPMENT TOOL (DDT) FOR ADDICTION MEDICINE: FROM CLINICAL AND EXPERIMENTAL EVIDENCE TO FDA STANDARDS***

*Hugh Garavan, University of Vermont*

**Summary Abstract:** There is a critical need for proxy measures of treatment response in drug addiction that are objective, sensitive, reliable and valid. FMRI drug cue reactivity (FDCR) is one of the very few proxy measures that has shown promising evidence to (1) cover three core elements of drug addiction (incentive salience, negative emotionality and cognitive control) in an ecologically validated context (drug cues), (2) predict abstinence (gold standard outcome), and (3) detect response to novel drugs that are relevant to clinical outcomes. There have been 42 clinical trials using FDCR as an outcome measure, and 318 published studies providing evidence for FDCR as a diagnostic, prognostic, predictive or treatment monitoring marker. However, FDCR is not qualified as a surrogate marker with the FDA, and to our knowledge no large multi-site phase 3 RCTs use FDCR. In this symposium we will explore the opportunities and challenges involved in qualifying FMRI measures as surrogate markers for drug development, and we will describe the current status of FDCR as such a marker. We will review empirical evidence about its replicability within subjects, consistency between subjects, its time course and its sensitivity to detect mechanistic changes in response to interventions. Speakers will include a complementary set of current FDCR practitioners and fMRI methodology experts. Throughout the talks, promising avenues for future work to further develop FDCR as a drug (intervention) development tool (DDT) will be identified.

## **21.1 INTER-INDIVIDUAL VARIATIONS IN NEURAL RESPONSES TO DRUG CUES**

Reagan Wetherill, *University of Pennsylvania*

## **21.2 LESSONS FROM DRUG CUE FMRI REACTIVITY TASKS IN HUMAN COCAINE ADDICTION: USING THE IRISA MODEL TO STUDY IMPACT ON HIGHER-ORDER EXECUTIVE FUNCTIONS**

Rita Goldstein, *Icahn School of Medicine at Mount Sinai*

## **21.3 INTEGRATING FMRI IN CLINICAL PHARMACOLOGY FOR ALCOHOL AND NICOTINE USE DISORDER**

Lara Ray, *University of California Los Angeles*

## **21.4 SENSITIVITY OF THE FMRI DRUG CUE-REACTIVITY TASK TO PHARMACOLOGICAL INTERVENTIONS IN COCAINE USE DISORDER: THE ROLE OF MODULATORS**

Jane Joseph, *Medical University of South Carolina*

**1:30 p.m. - 2:00 p.m.**

**MINI-SYMPOSIUM: CALLING TECH SUPPORT: TECHNOLOGY-FACILITATED INTERVENTIONS TO REDUCE SUBSTANCE USE AND ADVANCE HIV PREVENTION AND CARE**

Cathy Reback, *Friends Research Institute*

**Summary Abstract:** Given the proliferation of mobile phones, tablets, and computers, technology offers the option of immediate intervention delivery. The popularity of technology-facilitated interventions has increased in the field of addiction and HIV prevention and care. As mobile health (mHealth) and electronic health (eHealth) interventions are easily accessible, portable, convenient, and private, these modalities are particularly appealing to sexual (gay, bisexual, and other men who have sex with men) and gender (transgender and gender non-binary) minority individuals experiencing stigma and discrimination. This symposium will address a diversity of current, state-of-the-art technology modalities including mobile applications, WebApps, text-messaging platforms, and Internet-based recruitment strategies. Specific attention will be paid to the utilization of interventions grounded in evidence-based theoretical constructs that can be delivered through these technology modalities. Findings from technology-facilitated intervention studies with sexual and gender minority individuals will be presented. Further, the limitations of these interventions will be explored such as the (in)ability to impact structural barriers to treatment and care and the challenge of immediate linkage to either substance use or HIV treatment, especially among those who live at the intersection of poverty and housing instability. The symposium will conclude with an exploration of technology-facilitated intervention options for advancing the fields of addiction health services and HIV care.

**22.1 STIMULANTS, STIGMA, AND VIRAL SUPPRESSION AMONG SEXUAL MINORITY MEN ENROLLED IN AN E-HEALTH INTERVENTION**

Sabina Hirshfield, *SUNY Downstate Medical Center*

**22.2 USING MHEALTH TO CONNECT SUBSTANCE-USING MEN TO IMPROVE ART ADHERENCE**

Keith Horvath, *San Diego State University*

**22.3 TEXT-MESSAGING REDUCES METHAMPHETAMINE USE AND HIV RISKS AMONG MEN WHO HAVE SEX WITH MEN: AUTOMATED UNIDIRECTIONAL DELIVERY OUTPERFORMS BIDIRECTIONAL INTERACTIVE DELIVERY**

Cathy Reback, *Friends Research Institute*

**1:30 p.m. - 2:00 p.m.**

**MINI-SYMPOSIUM: CATALYST FOR CHANGE: NOVEL TREATMENTS IN SUBSTANCE USE DISORDER**

Megan Shram, *Altreos Research Partners Inc.*

**Summary Abstract:** Effective treatment of substance use disorders (SUDs) and withdrawal management continues to be a challenge and presents a large unmet medical need in the United States and worldwide. A common pharmacological approach includes substitution therapy, which relies on long-term administration and may be associated with abuse potential. However,

several novel treatments are under development for the treatment of various SUDs, which utilize different mechanisms and may have a different safety and abuse potential profile compared with existing treatments. This mini-symposium will highlight emerging data on three such products currently in clinical stages of development. The first presentation will focus on preclinical and clinical data which support development of noribogaine as a non-opioid alternative for the management of withdrawal symptoms following abrupt discontinuation. Noribogaine has shown antidepressant and anti-craving effects, which in low doses may be beneficial for attenuating symptoms associated with the post-acute withdrawal syndrome. The second presentation will focus on the discovery and development of selective and reversible aldehyde dehydrogenase 2 inhibitors for the treatment of alcohol and other SUDs. The final presentation will discuss a first-in-class treatment for methamphetamine addiction, for which there are no approved pharmacologic therapies. The approach is based on a highly selective immunotherapy that reduces the rate and extent of methamphetamine penetration into the CNS. This therapeutic approach will keep the patient from experiencing the effect of methamphetamine and may improve their ability to adhere to therapy while abstaining from methamphetamine.

### **23.1 MANAGING OPIOID DEPENDENCE WITH LOW-DOSE NORIBOGAINE**

Deborah Mash, *University of Miami Miller School of Medicine*

### **23.2 CATALYST FOR CHANGE: NOVEL TREATMENTS IN SUBSTANCE USE DISORDER**

Brent Blackburn, *Amygdala Neurosciences*

### **23.3 OLDER MECHANISMS, NEW LENS: NOVEL TREATMENTS IN SUBSTANCE USE DISORDER**

Lynn Webster, *PRA Health Sciences*

**2:00 p.m. - 2:55 p.m.**

#### ***WORKSHOP: EXPLORING THE CLINICAL UTILITY OF BIOMARKERS TO PERSONALIZE TREATMENT SERVICES FOR TOBACCO USE DISORDER***

Shelley (Zu-In) Su, *National Institute of Drug Abuse, National Institutes of Health*

**Summary Abstract:** Clinical research has made significant advances in characterizing biomarkers, defined as objective, measurable endpoints, for predicting tobacco use disorder (TUD) relapse. Yet, the clinical adoption of these measures to optimize treatment and cessation outcomes has been limited, if used at all. This delayed diffusion of knowledge from bench to clinical practice hinders health care providers' treatment decision making for their patients and may adversely impact patient outcomes. To address this implementation gap in TUD, we have convened a panel of experts to provide a current review of the leading biomarkers for predicting smoking cessation in genetics, nicotine metabolism, and digital phenotyping. Additionally, the panel will present a pragmatic conceptual framework to aid ongoing decision making about adoption of biomarker tools in clinical settings, thereby narrowing the implementation gap. To guide a discussion with the health services research community, panel experts will address pragmatic aspects of their biomarkers (e.g., relative performance of each biomarker against traditional clinical assessments, cost, ease and frequency of assessment). Finally, the discussant will summarize the science and lead a discussion on target outcomes for biomarker predictions

(stratified relapse risk, time to relapse, personalized response to pharmacotherapies, adverse consequences during recovery) and operational aspects of biomarker research (study design, sample size, health care setting). The intent of this panel is to survey enthusiasm for using biomarkers in guiding treatment decision making from the extramural SUD services research community, and to create recommendations for the field to accelerate and increase adoption of biomarker assessments into routine care.

#### **24.1 OPPORTUNITIES AND CHALLENGES FOR USING GENETICS TO PROMOTE SMOKING CESSATION**

Michael Bray, *Washington University in St. Louis*

#### **24.2 FUTURE CHALLENGES FOR PERSONALIZING TREATMENT FOR TOBACCO DEPENDENCE USING THE NICOTINE METABOLITE RATIO**

Robert Schnoll, *University of Pennsylvania*

#### **24.3 PERSONALIZED TREATMENTS FOR SUBSTANCE USE DISORDERS VIA DIGITAL HEALTH**

Lisa Marsch, *Geisel School of Medicine at Dartmouth*

#### **24.4 IMPLEMENTATION SCIENCE TO ACCELERATE THE USE OF BIOMARKERS FOR PERSONALIZED SMOKING CESSATION**

Alex Ramsey, *Washington University School of Medicine*

**2:00 p.m. - 2:55 p.m.**

#### ***SYMPOSIUM: STEPPING ON OR STEPPING OFF?: RECENT FINDINGS ON CANNABIS AND OPIOIDS IN MULTIPLE SETTINGS***

Meredith Meacham, *University of California San Francisco*

**Summary Abstract** The opioid epidemic in the United States is associated with dramatic increases in problematic opioid use and overdoses and there is considerable interest in determining whether cannabis and cannabinoid products are viable alternatives to opioids for pain management. A growing body of research has reported on the potential opioid-sparing effects of cannabis use, and medical cannabis patients report pain as the most common reason for use. On the other hand, studies also suggest that cannabis may increase the risk of prescription opioid misuse and opioid use disorder. There remain ongoing concerns regarding adolescent use of cannabis as well as the potential for concurrent use of cannabis to complicate opioid use disorder treatment. This symposium will focus on questions regarding the role of cannabis in "stepping on" to opioids vs. facilitating "stepping off" from opioids, drawing from laboratory, community, dispensary, and online settings and including contributions by several early career investigators. Dr. Thrul will present findings from a 12-year cohort study indicating that adolescent cannabis use increases the risk for opioid use in young adulthood. Dr. Meacham will present an analysis of online Reddit discussions about cannabis and opioids, contrasting perspectives from those actively using opioids with those in recovery. Dr. Cooke will present findings from a sample of cannabis dispensary patients demonstrating associations between levels of pain and cannabis consumption frequency, but not past-year change in health

status. Dr. Dunn will present results of a controlled lab study examining within-subject effects of dronabinol (THC) on opioid abuse potential and pain.

### **25.1 ADOLESCENT CANNABIS USE INCREASES THE RISK FOR OPIOID USE IN YOUNG ADULTHOOD - 12-YEAR LONGITUDINAL ASSOCIATIONS IN AN URBAN COHORT**

Johannes Thrul, *Johns Hopkins Bloomberg School of Public Health*

### **25.2 DIGITAL PERSPECTIVES ON CANNABIS USE IN ONLINE OPIOID AND OPIOID RECOVERY COMMUNITY DISCUSSION FORUMS**

Meredith Meacham, *University of California San Francisco*

### **25.3 THE RELATIONSHIP BETWEEN LEVELS OF CHRONIC PAIN AND CONSUMPTION OF CANNABIS AND CHANGES IN HEALTH AMONG MEDICAL CANNABIS PATIENTS**

Alexis Cooke, *UCSF School of Medicine*

### **25.4 HUMAN LABORATORY EXAMINATION OF DRONABINOL'S EFFECTS ON HYDROMORPHONE ABUSE POTENTIAL AND PAIN OUTCOMES**

Kelly Dunn, *Johns Hopkins University School of Medicine*

**3:00 p.m. - 3:30 p.m.**

### ***MINI-SYMPOSIUM: ARTIFICIAL INTELLIGENCE TECHNOLOGIES TO ENABLE DRUG DEVELOPMENT FOR SUBSTANCE USE DISORDERS***

Susan Wright, *NIDA/NIH*

**Summary Abstract:** In 2017, it was estimated that more than 19 million Americans aged 12 or older met the criteria for a substance use disorder (SUD). There remains a significant need for new pharmacotherapeutics to treat addiction and new approaches for drug discovery and development. The new technological revolution in artificial intelligence (AI) will help meet this need. AI algorithms can analyze huge databases of chemical, biological, medical, published literature and electronic health records (EHRs) to find new drug treatments, diagnose disease, and personalize healthcare. These algorithms will be able to make predictions about individuals and their substance use patterns. This information can be leveraged to discover potential new drugs, diagnose addiction, and personalize treatment. It can also be used to develop new biomarkers of addiction to breakdown the clinical and biological complexity for diagnosis and enhance drug development via improved clinical trial design. Research to be presented will show the ability of AI technologies for: (i) personalized drug discovery; (ii) repurposing drugs as potential new treatment options; and the (iii) discovery of drug combinations to treat addiction and co-morbidities. Presentations will cover findings from a range of AI technologies and approaches, including natural language processing, text mining, machine learning, data mining, knowledge representation, network-based modeling, and prediction and patient EHR mining. The goal of this mini-symposium is to showcase how powerful new advances in AI technology will greatly enhance addiction research and enable new drug discovery.

## **26.1 DEVELOP KNOWLEDGE-DRIVEN EXPLAINABLE AI-HUMAN-ANIMAL REINFORCEMENT LEARNING MACHINES FOR DRUG DISCOVERY**

Rong Xu, *Case Western Reserve University, School of Medicine*

## **26.2 COMBINING BIG DATA ANALYTICS WITH EXPERIMENTATION AND GENOME PROFILING TO ACCELERATE DRUG DISCOVERY**

Olivier Elemento, *Weill Cornell Medical College*

## **26.3 HIGH-THROUGHPUT PROPENSITY SCORE WEIGHTING TO IDENTIFY DRUG COMBINATIONS FOR CANCER PREVENTION**

Xiaoqiang Jiang, *University of Texas Health Science Center at Houston*

**3:00 p.m. - 3:30 p.m.**

### ***MINI-SYMPOSIUM: SUBSTANCE USE BEHAVIORS AMONG SEXUAL AND GENDER MINORITY INDIVIDUALS: A MULTI-LEVEL AND MIXED-METHODS APPROACH***

Morgan Philbin, *Columbia University Mailman School of Public Health*

**Summary Abstract:** Sexual and gender minorities (SGMs) experience elevated rates of substance use and disordered use compared to heterosexuals, including tobacco, marijuana, alcohol, prescription drug misuse, and illegal drug use. Importantly, SGMs are not a homogenous group, and analyses demonstrate significant differences across age, gender and sexual identity (gay/lesbian vs. bisexual); substance use disparities are particularly stark for transgender individuals and bisexual women. Drivers of these disparities occur at the structural-, community- and individual-level. Examples of these drivers include sexual minority stress—that sexual orientation-based health disparities result from sexual minorities’ exposure to stigma and discrimination—state-level policies (e.g., around sexuality-based discrimination, marijuana, and housing), community-level norms, and treatment access. This mini-symposium will present mixed-methods findings on youth and adults from the US and Canada. Dr. Schuler will describe results from the National Survey on Drug Use and Health (NSUDH) that indicate the heterogeneity of substance use disparities among sexual minority adults, highlighting important differences by age, gender and identity. Dr Knight will present qualitative findings from a program of research identifying how young sexual minority men in Canada navigate substance use in the context of the opioid overdose crisis and a highly contaminated drug supply. Lastly, Dr. Philbin will share mixed-methods findings from the NSDUH and qualitative interviews across 25 US states that highlight the multi-level drivers of substance use among SGMs, including the mechanisms through which these drivers differentially impact SGMs. We will conclude with discussions of next steps for substance use research among SGMs, including potential intervention targets.

## **27.1 HETEROGENEITY IN SUBSTANCE USE DISPARITIES AMONG SEXUAL MINORITY ADULTS BY AGE, GENDER AND SEXUAL IDENTITY**

Megan Schuler, *RAND*



## **27.2 A DEEPER DIVE INTO THE EXPERIENCES OF YOUNG SEXUAL MINORITY MEN WHO USE SUBSTANCES IN CANADA**

Rod Knight, *University of British Columbia*

## **27.3 MULTI-LEVEL DRIVERS OF SUBSTANCE USE DISPARITIES FOR SEXUAL AND GENDER MINORITIES: A MIXED-METHODS EXPLORATION**

Morgan Philbin, *Columbia University Mailman School of Public Health*

**3:30 p.m. - 4:30 p.m.**

### ***TOWN HALL FORUM: GETTING YOUR INVESTIGATIONAL NEW DRUG (IND) AND INVESTIGATIONAL DEVICE EXEMPTION (IDE) APPLICATIONS APPROVED BY THE FOOD AND DRUG ADMINISTRATION (FDA)***

Ajna Hamidovic, *University of Illinois*

**Summary Abstract:** This Town Hall, offered by the Industry, Government, and Academia Committee, will focus on navigating the regulatory path toward filing and approval of investigational new drug (INDs) and Investigational Device Exemption (IDE) applications for small molecules, biologics, and medical devices for Substance Use Disorders (SUDs). Sponsor-Investigators seeking to initiate clinical trials often lack the resources to hire regulatory experts to assist with the IND or IDE process. This Town Hall addresses this topic in a four-part presentation followed by Q&A with the audience. In Part I, Dr. Hamidovic will discuss the IND review process and general responsibilities of Sponsor-Investigators related to clinical investigations. Drawing on her experience in obtaining IND approval for intranasal insulin, she will focus on efficient strategies to address clinical holds and requests for modifications. In Part II, Dr. Pravetoni will focus on translation of biologics to treat OUD and share his experience in filing an IND to support clinical evaluation of an anti-opioid vaccine. In part III, Dr. Rocha will focus on the process of filing an IDE to support clinical evaluation of medical devices. In Part IV, Dr. Taylor will discuss the process and requirements related to moving a newly discovered small molecule from the laboratory, through early stage nonclinical development, and into the clinic for early stage clinical evaluation. Collectively, different perspectives from regulators, industry, and academia will encourage a lively debate to inform the audience on advancing their IND/IDE for SUD.

## **28.1 NOSE-TO-BRAIN NEUROPEPTIDE INVESTIGATIONAL PRODUCT APPROVAL PROCESS**

Ajna Hamidovic, *University of Illinois*

## **28.2 FROM PRE-CLINICAL STUDIES TO IND TO SUPPORT TRANSLATION OF ANTI-OPIOID VACCINES AND MONOCLONAL ANTIBODIES**

Marco Pravetoni, *University of Minnesota Medical School*

**5:00 p.m. - 5:55 p.m.**

### ***WORKSHOP: TECHNOLOGICAL ADVANCEMENTS OF HUMAN CELL-BASED STUDIES FOR SUD RESEARCH***

Da-Yu Wu, *National Institute on Drug Abuse, National Institutes of Health*

**Summary Abstract:** Recent technological advancements have allowed generating active neural circuits in three dimensional cultures such as cerebral organoids and neural networks in microphysiological systems (MPS), using human induced pluripotent stem cell (iPSC) lines. Cells in these cultures demonstrate the characteristics of those developed in vivo, in gene transcription, cell migration, neuronal connections, activities and responses to stimuli. Three-dimensional cultures allow multi-level analysis of complex neurodevelopmental processes because they recapitulate the development of complex, organ-like tissues reminiscent of those of human brain. Indeed, cerebral organoids from iPSC of neurological disease patients have been used to study cellular and molecular defects, and to image cell activities, at the single cell level in a physiologically relevant background, and to test potential therapeutic compounds. This symposium will present several state-of-art human cell-based projects that use MPS and organoid cultures to study the cellular and molecular mechanisms of substance use disorders (SUD). Dr. Maidment will describe a human cell derived brain circuitry that provides mechanistic insight into the opiate-mediated addictive process. Dr. Walss-Bass will demonstrate an addiction MPS model developed in her laboratory, together with neuronal cells isolated from postmortem brain, to examine brain cell signaling and gene networks in opioid addiction. Dr. Keung will talk about creating human cell-derived organoids containing substance-responsive brain regions and functional connections between them to model a mesolimbic-like pathway with roles in addiction. Finally, Dr. Hickman will present building overdose models for opiates in a multi-organ system and evaluate the acute and repeat doses, or chronic effects, of overdose treatments.

#### **29.1 DEVELOPMENT OF HUMAN IPSC-DERIVED MICROPHYSIOLOGICAL SYSTEMS FOR MODELING DOPAMINERGIC RESPONSE TO CHRONIC OPIOID EXPOSURE**

Nigel Maidment, *Semel Institute for Neuroscience & Human Behavior at UCLA*

#### **29.2 COMBINED HIPSC-DERIVED MPS AND HUMAN POSTMORTEM SINGLE-CELL ANALYSES TO MODEL MECHANISMS OF COCAINE AND OPIOID NEUROTOXICITY**

Consuelo Walss-Bass, *The University of Texas Health Science Center at Houston*

#### **29.3 MULTI-ORGAN HUMAN-ON-A-CHIP SYSTEM TO ADDRESS OVERDOSE AND ACUTE AND CHRONIC EFFICACY AND OFF-TARGET TOXICITY**

James Hickman, *University of Central Florida*

#### **29.4 CELLULAR AND MOLECULAR TOOLS FOR EX VIVO, HUMAN, MESOLIMBIC-LIKE MODELS**

Albert Keung, *North Carolina State University*

**5:00 p.m. - 5:55 p.m.**

#### **WORKSHOP: 26TH ANNUAL CONTINGENCY MANAGEMENT WORKING GROUP**

August Holtyn, *Johns Hopkins University School of Medicine*

**Summary Abstract:** The Contingency Management (CM) Working Group, held annually during the CPDD convention, is an opportunity for the discussion and dissemination of current

research regarding the use of CM interventions to promote behavior change and reduce drug use. CM is a behavioral treatment strategy that has demonstrated consistent success in promoting abstinence from a wide range of drugs and across many different treatment populations. It is also being used to promote change in behaviors impacting the course of other chronic diseases (e.g., obesity, diabetes). At the 26th annual meeting of the CM Working Group, presenters will discuss findings from studies involving CM. The goal for this working group is to provide an informal outlet for discussion of ongoing CM research, with an emphasis on developing or improving research strategies by seeking audience input, and providing opportunities for researchers to interact. As the goal for this working group has always been to provide an informal outlet for discussion of CM data, participants and topics will be chosen during the Spring of 2020 to capture the most current data in contingency management for presentation at our annual working group.

### **30.1 IMPLEMENTING CONTINGENCY MANAGEMENT WITHIN OPIOID TREATMENT PROGRAMS: PRELIMINARY FINDINGS FROM A TYPE 3 HYBRID TRIAL**

Bryan Garner, *RTI International*

### **30.2 BIOSENSOR-CORROBORATED CONTINGENCY MANAGEMENT INTERVENTION FOR ALCOHOL ABSTINENCE IN OLDER ADULTS WITH AND WITHOUT HIV INFECTION AND HEAVY DRINKING**

Veronica Richards, *University of Florida*

### **30.3 TREATING PTSD IN PATIENTS WITH OPIOID USE DISORDER: USING INCENTIVES TO PROMOTE THERAPY ATTENDANCE**

Kelly Peck, *University of Vermont*

### **30.4 LEARNING AND INCENTIVE SENSITIVITY IN COCAINE USERS: LINKS TO CONTINGENCY MANAGEMENT OUTCOME AND STRIATAL DOPAMINE SIGNALING**

Nehal Vadhan, *Zucker School of Medicine at Hofstra/Northwell*

**6:00 p.m. - 6:55 p.m.**

### ***WORKSHOP: EPIDEMIOLOGY AND PUBLIC HEALTH RESEARCH METHODS***

Howard Chilcoat, *Indivior, Inc.*

**Summary Abstract:** This proposal is for a continuation of the annual CPDD Epidemiology and Public Health Research Methods evening workshop series that was launched more than 10 years ago. This year's workshop will feature a series of methodologic approaches of interest to those conducting epidemiologic, prevention, and clinical research in the field of drug use and related disorders. Topics to be discussed include: 1) Beth Ann Griffin, RAND - Can't shake that feeling you forgot something? Assessing sensitivity of findings to omitted variable bias; 2) Megan Shuler, RAND - Identifying the best models for state-level opioid policy analyses; 3) Ahnalee Brincks, Michigan State University - Introduction to Adaptive Interventions and their applications to substance use; 4) Kate Guastaferrro, Pennsylvania State University - Introduction to multiphase optimization strategy for behavioral intervention research.

### **31.1 CAN'T SHAKE THAT FEELING YOU FORGOT SOMETHING? ASSESSING SENSITIVITY OF FINDINGS TO OMITTED VARIABLE BIAS**

Beth Ann Griffin, *RAND Corporation*

### **31.2 IDENTIFYING OPTIMAL METHODS FOR OPIOID POLICY RESEARCH**

Megan Schuler, *RAND*

### **31.3 INTRODUCTION TO MULTIPHASE OPTIMIZATION STRATEGY FOR BEHAVIORAL INTERVENTION RESEARCH**

Kate Guastafarro, *Penn State University*

### **31.4 INTRODUCTION TO ADAPTIVE INTERVENTIONS AND THEIR APPLICATIONS TO SUBSTANCE USE**

Ahnalee Brincks, *Michigan State University*

**6:00 p.m. - 6:55 p.m.**

### ***WORKSHOP: EVIDENCE BASED SELECTION OF PATIENTS AND OUTCOMES IN CLINICAL TRIALS: TOWARDS AN FDA APPROVED MEDICATION FOR STIMULANT USE DISORDER***

Tatiana Ramey, *National Institutes of Health*

**Summary Abstract:** Numerous clinical trials for cocaine and methamphetamine use disorders have been unsuccessful in meeting their primary outcome target of eliminating positive urine drug screens at the end of the study. Several issues have been proposed as the cause of these failed trials. This symposium will explore evidence that patient-centric approaches to selection of outcome measures and sub-groups that may be more likely to respond to these outcome measures could result in development of effective treatments for stimulant use disorders. F. Gerard Moeller will discuss development of patient-centric outcome measures, using examples from other disorders, such as Nonalcoholic steatohepatitis, (NASH) in collaboration with the FDA, patients, and non-profit organizations. Brian Kiluk will discuss evidence-based candidate endpoints for stimulant use disorders that are alternatives to urine drug screen-based outcomes in clinical trials. Kris Bough from NIDA will discuss biomarkers that have been used in development of medications for other disorders as examples of patient selection for clinical trials and how these biomarkers could be chosen based on alternative treatment outcomes. Christopher O. St. Clair from the FDA/CDER will discuss the FDA perspectives on patient-centered outcome measures in clinical trials.

### **32.1 EVIDENCE-BASED CANDIDATE ENDPOINTS FOR STIMULANT USE DISORDERS**

Brian Kiluk, *Yale University School of Medicine*

### **32.2 WHEN “ONE SIZE DOESN'T FIT ALL”**

Anna Childress, *University of Pennsylvania Perelman School of Medicine*

### **32.3 FDA PERSPECTIVES ON ALTERNATIVE TREATMENT OUTCOMES**

Christopher St. Clair, *FDA Office of New Drugs*

### **32.4 PATIENT-CENTRIC OUTCOME MEASURES FOR STIMULANT USE DISORDER CLINICAL TRIALS**

F. Gerard Moeller, *Virginia Commonwealth University*