

EXPLORING THE ETHICAL AND PRACTICAL CONSIDERATIONS OF PSYCHEDELICS RESEARCH

THURSDAY, SEPTEMBER 14, 2023 | NORTH BETHESDA, MARYLAND

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2023 OHRP EXPLORATORY WORKSHOP



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INTRODUCTION

INTRODUCTION

Psychedelics are powerful psychoactive substances that alter perception and mood and affect numerous cognitive processes. Their origins predate written history, and early cultures used them in many sociocultural and ritual contexts. The name 'psychedelics' was coined by Humphrey Osmond in 1957, suggesting that they have a mind-manifesting capability that may reveal useful or beneficial properties of the mind. For decades, psychedelics have been classified as illegal drugs. Recent research suggests that these substances may provide a potential breakthrough in the treatment of a myriad of mental health conditions. This exploratory workshop will examine the ethical and practical considerations for psychedelics research with the goal of promoting an open and grounded discourse on how to conduct research that is inclusive and protective of participants.

OBJECTIVES

The purpose of OHRP's Exploratory Workshop is to provide a platform for open dialogue and exchange of ideas between stakeholders in the regulated community. This workshop on psychedelics research will:

- Explore the ethical considerations and legal concerns pertaining to the use of psychedelics.
- Review some of the practical challenges with conducting research with psychedelics, including the challenges of including certain population groups as participants.
- Discuss issues that may have an impact on preserving public trust for ensuring the advancement of psychedelics research.

AGENDA

Time	Sessions
9:45 AM – 10:00 AM	Welcome
10:00 AM – 11:25 AM	Session I: Ethics and Law Moderator: Holly Fernandez Lynch, J.D., M.BE.; <i>Assistant Professor of Medical Ethics and Law, University of Pennsylvania</i>
	Psychedelics in Therapeutic Research: Expanding the Scope of Healing Duff Waring, LL.B., Ph.D.; <i>Professor, Department of Philosophy, York University</i>
	Research, Referendum, Litigation, and Legislation: Picking the Locks on the Doors of Perception Noah Potter, J.D.; <i>Legal Market Strategies</i>
	Beyond Compliance: Building a Comprehensive Ethics Infrastructure in Psychedelics Research With Human Participants Dominic Sisti, Ph.D.; <i>Associate Professor of Medical Ethics & Health Policy, Department of Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania</i>
	What Are the Ethical Challenges With Obtaining Informed Consent for Participation in Psychedelics Research? Andrew Peterson Ph.D.; <i>Assistant Professor, Department of Philosophy, Institute for Philosophy and Public Policy, George Mason University</i>
11:25 AM – 12:10 PM	Panel Discussion
12:10 PM – 12:50 PM	Lunch
12:50 PM – 2:15 PM	Session II: Considering Practical Aspects of Psychedelics Research Moderator: Benjamin C. Silverman, M.D.; <i>Senior IRB Chair, Mass General Brigham, Director of Ethics, McLean Institute for Technology in Psychiatry, McLean Hospital, Instructor in Psychiatry and Faculty Member in the Center for Bioethics, Harvard Medical School</i>
	What Are the Challenges in Designing Scientifically Sound Clinical Trials for Examining the Effects of Psychedelics? Rachel Yehuda, Ph.D.; <i>Professor of Psychiatry and Neuroscience, Director, Center for Psychedelic Psychotherapy and Trauma Research at Icahn School of Medicine at Mount Sinai; Director of Mental Health at the James J. Peters Veterans Affairs Medical Center</i>
	What Are the Challenges With Evaluating and Minimizing the Risks of Research Involving Psychedelics? Natalie Gukasyan, M.D.; <i>Assistant Professor, Columbia University School of Medicine</i>
	Exploitation or Inclusion? Exploring the Ethical Obligation and the Unique Challenges With Including Black and Brown Populations in Psychedelic Research Darron Smith, Ph.D., PA-C, DFAAPA; <i>Associate Program Director, Research and Scholarship at MEDEX; Co-Director for the Center for Novel Therapeutics in Addiction Psychiatry</i>
	Addressing the Challenges With Conducting Psychedelics Research Involving Criminal Justice-Involved Populations Logan Neitzke-Spruill, Ph.D.; <i>Postdoctoral Associate, Center for Medical Ethics and Health Policy, Baylor College of Medicine</i>

AGENDA

Time	Sessions
2:15 PM – 3:00 PM	Panel Discussion
3:00 PM – 3:10 PM	Break
3:10 PM – 3:55 PM	Session III: Safeguarding Public Trust; Preventing Another Psychedelics Bubble Moderator: R. Cameron Wolf, Ph.D.; <i>Senior Advisor, CSAP/Office of Prevention Innovation, DHHS/SAMHSA</i>
	Rosalind Watts, Ph.D.; <i>Founder, ACER Integration</i> Dr. Watts will detail her journey as a psychotherapist whose position shifted from buying the psychedelics hype to being agnostic about the promising potential of using magic mushrooms to treat depression.
	Juliana Mercer; <i>United States Marine Corps Veteran, Political Advocate in Promoting Safe Access for Veterans to MDMA and Psychedelics for the Treatment of PTSD</i> Ms. Mercer will provide perspectives as an advocate, a veteran who healed her PTSD with psychedelics, a member of the Board of Directors for a psychedelic veteran nonprofit, and a coach to veterans pursuing psychedelic journeys in countries where they are not illegal.
	Laura Sanders, Ph.D.; <i>Senior Writer, Science News Magazine</i> Dr. Sanders will reflect on the role that media plays in reporting about psychedelics' effects on mental illness and offer advice to scientists and policymakers on how to communicate with the public to combat misinformation.
	Yuria Celidwen, Ph.D.; <i>University of California, Berkeley, Department of Psychology and Othering & Belonging Institute</i> Dr. Celidwen will provide insight on how usage of psychedelics in Western medical practices may impact the Indigenous peoples who originated psychedelic medicine and offer suggestions for relationship-building between the two groups.
3:55 PM – 4:15 PM	Panel Discussion

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Exploring the Ethical and Practical Considerations of Psychedelics Research Exploratory Workshop: September 14, 2023

Welcome and Introduction

- Leith States, MD, MPH, Chief Medical Officer, Office of the Assistant Secretary for Health (OASH)
- Julie Kaneshiro, MA, Acting Director, Office of Human Research Protections (OHRP), U.S. Department of Health and Human Services (DHHS)
- Yvonne Lau, MBBS, MBHL, PhD; Director, Division of Education and Development, OHRP

Dr. Lau expressed her excitement at having such a distinguished panel to address this timely topic. She noted that the event was being live streamed across the world and expressed hope that the research community will benefit from this exploratory workshop, the sixth in a series sponsored by OHRP's Division of Education and Development. She then introduced Dr. States.

Dr. States praised OHRP's efforts to organize the conference and said it was both an honor and a pleasure to be present. He noted the density of expertise present and the shared commitment to address a critical topic. Society has an interest in what it means to be well and whole, and psychedelics offer an important new healing modality that may be helpful to people with major depressive disorders, post-traumatic stress disorder (PTSD), substance abuse disorders (SUDs), and anxiety.

Dr. States said he is aware, however, that mentioning psychedelics can be polarizing. He expressed hope that the field will be able to listen thoughtfully to what science is telling us as we move toward translating research into practice. As one who has experienced PTSD, Dr. States understands what it is like to feel "trapped in the box" of one's own mind and hopes that both science and patients will be respected as we consider research findings through a lens of restoration.

Acting OHRP Director Julie Kaneshiro welcomed speakers and audience members, stressing that OHRP staff were present to listen, learn, and explore the issues raised. She thanked members of the Division of Education and Development for their dedication and leadership.

Session I: Ethics and the Law

- *Moderator:* Holly Fernandez Lynch, JD, MBE, Assistant Professor of Medical Ethics and Law, University of Pennsylvania

Session I Introduction

- Holly Fernandez Lynch

Professor Fernandez Lynch observed that OHRP's sponsorship of this workshop sends a critical signal to the field. Ethical psychedelics research must build on Indigenous knowledge and take into account the legal framework in which research takes place. The aim is to

maximize benefits and minimize harms while avoiding excessive hype, overpromising, and conducting research without adequate protection for subjects.

Psychedelics in Therapeutic Research: Expanding the Scope of Healing

- Duff Waring, LLB, PhD, Professor, Department of Philosophy, York University

High doses of psychedelics can induce an ego-dissolving experience that some call mystical. In addition to claims of transcending space and time, people report losing the sense of being a separate, individual self and experiencing an ecstatic sense of unity with a benevolent ultimate reality. Some describe this as a deeply meaningful, spiritual experience, even as an encounter with God, that enhances their quality of life and personal well-being. For others, higher doses can induce a traumatic experience that might worsen a preexisting condition like PTSD.

Psychedelic therapy is the mode of drug-assisted psychotherapy that aims to induce an ego-dissolving, mystical experience as the main driver of therapeutic benefit. It is being studied as a possible treatment for depression, PTSD, addictions, and anxiety related to life-threatening illness. Outcomes are highly influenced by the context in which the drug is taken. Careful preparation for the experience is essential, as the person's beliefs and expectations are important determinants of their response to a psychedelic. Preliminary sessions should enable persons to be receptive to the mystical experience and prepare them for possible adverse consequences. Integration sessions following the experience should help the person use it as a catalyst for ongoing positive change.

This framework has implications for research design: In addition to drug effects, we also have to study the psychotherapeutic processes that may prepare patients for a mystical experience and then help them integrate its benefits into better ways of living. This is critical to evolving the safest and most effective approaches to therapy.

Some researchers object to the cultural biases and metaphysical assumptions of the mystical-type experience. Historically, psychiatry has often pathologized it; for example, it may be called a temporal lobe dysfunction or seen as symptomatic of borderline psychosis. While psychedelics can elicit some experiences that are similar to symptoms of psychosis, they can also elicit meaningful insights of therapeutic value. As an approach to therapy, psychedelic-assisted therapy challenges those who are committed primarily to biological cures. The psychotherapy that precedes and follows the drug session is thought to be as crucial to therapeutic benefit as the drug itself.

The main stimulus for positive change from a mystical experience is thought to be its ego-dissolving effect. One theory is that uprooting the self may allow persons to reconceive of themselves in new and better ways; i.e., outside of the problematic thoughts, feelings, and behaviors which formerly hampered them. Possible outcomes include uplifting changes to one's spiritual beliefs about a greater, transpersonal reality; a sense of feeling more at home in the world; an expanded sense of possibilities; or a greater acceptance of death and dying. Some would characterize these as comforting delusions. Dr. Waring suggested that they are better understood as acceptable ways of trying to lead a meaningful life. The possible benefits of psychedelic therapy overlap significantly with beneficial insights that may be achieved in

traditional psychotherapies. With enhanced neuroplasticity, patients may experience reduced symptoms, heal trauma, or better understand their relationships.

Dr. Waring stressed that psychedelic therapy is not just about the drug experience; preparation sessions and post-trip integration work are essential components of real and lasting healing. What one does with a psychedelic experience appears to be more important to sustaining and developing benefit than simply having it. He noted the current effort to clarify the theory and practice of post-trip integration work. Psychedelics don't do the healing for us. Expectations of a magic-bullet cure, often picked up and exaggerated by the media, are not helpful. If approved for clinical use in psychiatry, psychedelics could play a role in an expanded approach to healing that better addresses spiritual concerns and resuscitates a greater role for psychotherapy.

Research, Referendum, Litigation, and Legislation: Picking the Locks on the Doors of Perception

- Noah Potter, JD, Legal Market Strategies

Mr. Potter, a practicing attorney, sees psychedelics law as a unique area of law rather than as a part of law related to drugs. State legislators are showing interest in the therapeutic use of psychedelics. There is a rapidly growing movement to remove criminal penalties for actions involving psychedelics under state or local law, including facilitating access through state-licensed delivery systems. Pending research-focused legislation in Pennsylvania would mandate creation of an Institutional Review Board (IRB) with a specialty in psychedelics, while proposed New York legislation would create a public option IRB for independent researchers and those working through clinics with limited funding. Texas, Connecticut, and Maryland have established study groups on the possible health benefits of therapies involving specific psychedelic substances. Such options often receive bipartisan support, in part because of the vocal support of veterans' groups that believe these drugs may relieve the symptoms of PTSD.

The longstanding, well-evolved psychedelic-using population is also a prime mover of the legislative reform advocacy that is sweeping local and state governments. However, that movement is suffused with concern about a "takeover" by commercial or government forces. Some are suspicious of, or even hostile to, clinical research, which they may perceive as supporting a strictly medical market to which they are opposed.

Defining psychedelics. What are psychedelics? The term is from the Greek and means, approximately, "mind manifesting." The classification is imprecise, but it is generally understood to refer to a range of psychoactive substances, including lysergic acid diethylamide (LSD), psilocybin, N,N-dimethyltryptamine (N,N-DMT or DMT), mescaline, ibogaine, and bufotenine. Colloquially, the term encompasses MDMA (3,4-methylenedioxymethamphetamine, commonly known as "ecstasy" or "molly") and ketamine, although both differ in their action and effects from the "classic" psychedelics. Some constituencies prefer the term "entheogen," which can be translated as "generating God within."

Mr. Potter holds that psychedelics are categorically different from other psychoactive substances in their subjective effects. They are unique in that they fuse medicine with religion or spirituality, inducing mystical (or at least spiritual) experiences. They can be characterized as “cognitive technologies” with extremely powerful effects that may result in changes in behavior or personality. Today, they are being promoted as hot new biotech investments, and billions of dollars are pouring into the medical market to promote sales that benefit for-profit pharmaceutical companies and investors.

Future directions. The “hype” around pharmaceuticals is now coming not just from advocates and subjects, but also from the for-profit sector, which has its own motivation. The consequences of mass use of psychedelics (a scenario for which there is no precedent) are unknown. Mr. Potter noted that cannabis legalization in New York led to an eruption of unlicensed retail venues in New York City. Psilocybin mushrooms now are sold openly in certain venues, perhaps corresponding to the media characterization of psilocybin mushrooms as “the new cannabis.”

Reports of relatively high efficacy and relatively low risk profiles of psychedelic substances emanating from clinical research may contribute to the hype, both by spurring investment in the pharmaceutical sector and increasing activity in the illegal market. Findings may increase interest in psychedelics among people seeking relief or new experiences. It is not clear to what extent the extensive but anecdotal experiences of people who have used these substances will be recognized in formulating safety and efficacy standards under federal law.

Beyond Compliance: Building a Comprehensive Ethics Infrastructure in Psychedelics Research with Human Participants

- Dominic Sisti, PhD, Associate Professor of Medical Ethics and Health Policy, Department of Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania

Dr. Sisti’s presentation was guided by the following questions:

- Where does psychedelics research fit within the history of research ethics?
- What resources might bioethics have to offer this new field of mental healthcare as it moves from clinical research to clinical practice?
- How should the principles of the *Belmont Report* inform a more comprehensive ethical framework for psychedelics research and practice that goes beyond mere compliance?
- How might the principles of fairness, equity, public trust, reciprocity, and transparency buttress this ethical framework?

Dr. Sisti noted that initial enthusiasm for LSD was accompanied by studies with questionable ethics, resulting in concern about and restrictions on future studies. Seeking an ethical framework for responsible studies, Dr. Sisti centered his remarks on the core principles of the *Belmont Report*—respect for persons, beneficence, and justice. He observed, however, that research leaders in this field often have little contact with mainstream bioethics, and until recently practitioners of mainstream medicine had little interest in pursuing research with highly stigmatized substances. In addition to the framework of Belmont principles, Dr. Sisti

called for respect for ethical principles associated with traditional Indigenous medicine, which can guide Western psychedelics research and practice (Celidwen et al., 2023). However, these principles are not easy to honor in a capitalist society.

Respect for persons. The first Belmont principle, respect for persons, calls for protection for subjects, with particular concern for vulnerable persons. Research subjects who are recruited for therapeutic psychedelic use often have serious mental conditions. Dr. Sisti queried, “Do novel aspects of psychedelics research and treatment require a different kind of informed consent process? If so, what should it look like?” Reality checking is a must, given the needs and hopes subjects bring to psychedelic experiences.

Dr. Sisti observed that psychedelic therapy may cause a variety of experiences uncommon in other therapies. For example:

- Patients report these experiences as among the most important of their lives.
- Patients may experience dramatic changes in self-understanding, self-efficacy, relationships, and long-held values.
- Transformative experiences—ones in which the future is unknown—complicate standard models of decision making.

These considerations require a deep conversation and are well beyond what can be conveyed in a simple form. Dr. Sisti noted that some personality changes that could occur may be unwelcome. For example, subjects could experience psychosis and be retraumatized instead of healed, and preparatory sessions should address these possibilities. The speaker queried:

- Are standard models of informed consent adequate in psychedelics research and treatment?
- How should researchers disclose or communicate about ineffable experiences?
- Should researchers be required to auto-experiment?
- How might researcher enthusiasm affect outcomes and evidence?
- How should researchers discuss potential personality changes?
- What should happen when participants change their minds about things they agreed to in the informed consent process while they are in a non-ordinary state?
- How do we assess risk/benefit in minors and incapacitated individuals?

The principle of respect for persons also demands attention to “hope vs. hype.” Some prospective subjects may enter studies hoping for a complete cure to mental illness. Others expect such experiences to end social malaises, war, and racism. Public understanding provides a baseline for informed consent.

Beneficence. The principle of beneficence is also relevant in such studies, calling for careful risk/benefit analysis and consideration of both the psychological and physical safety of study participants. Dr. Sisti posed the following questions: How can we design studies that minimize risk? How can we maintain safe clinical research environments? What are appropriate boundaries? What does it mean to have competency as a psychedelics researcher and

practitioner? Who should be in the room? He noted as well that there have been cases of sexual abuse, raising questions around the appropriate use of touch. In the field of psychedelics research, ethics are in the nascent stage.

To date, participants in research on psychedelics have been mostly white men. Clearly, diversity is essential in future subject populations. On the other hand, physical settings have varied widely across study sites, creating complexity in measuring outcomes. Therapist orientation, training, personal experience, and competence also have varied widely across study sites. Dr. Sisti noted that further complexity is introduced by the fact that it is virtually impossible to carry out a gold standard double blind study, since it is usually obvious to participants that they have had an unusual experience.

The issue of therapeutic touch—touch that is aimed at minimizing harm, ensuring safety, or increasing efficacy—is more complicated than sexual touch, which is never appropriate in a research setting. For patients who consent and may be struggling with a non-ordinary state, certain kinds of touch may be effective in helping them return to calm.

On the other hand, well-intended but misapplied touch could trigger or worsen a trauma response. Therapeutic touch requires virtuous, well-trained, and competent professionals. Currently, there is inadequate screening, credentialing, and oversight of psychedelic practitioners, and there is no clear way to lodge complaints or investigate allegations of wrongdoing. Until these structures are built and fully functional, participants and patients will be vulnerable.

Justice. The third Belmont principle, justice, calls for equitable selection of subjects and access to research, reciprocity, and attention to legal and ethical considerations that may apply at the local level. In the case of psychedelic substances, many of which are considered holy by Indigenous people, justice demands that findings be shared with them. Dr. Sisti challenged the audience by asking: How can we make access to these medicines broad, easy, and equitable? What do participants in psychedelic capitalism owe Indigenous persons for their knowledge?

As noted above, subject selection has been biased. Most research participants have been white men. Black, Indigenous, and People of Color Communities (BIPOC) are understandably mistrustful, given the legacy of unethical research combined with discriminatory enforcement of drug laws. However, the burden of PTSD and other conditions that may be addressed through psychedelic therapies is high in BIPOC communities. Equitable access to psychedelics research and treatment is important, and major research organizations have a responsibility to build a solid ethical foundation in this space.

What Are the Ethical Challenges with Obtaining Informed Consent for Participation in Psychedelics Research?

- Andrew Peterson, PhD, Assistant Professor, Department of Philosophy, Institute for Philosophy and Public Policy, George Mason University

Dr. Peterson focused his remarks on three questions:

- What are transformative experiences?

- How might transformative experiences complicate informed consent?
- Do psychedelics induce transformative experiences? Even if they do, does this complicate informed consent?

While many bioethics scholars believe that transformative experiences are induced by psychedelic substances and that they pose unique problems for the informed consent process, Dr. Peterson challenged both of these assumptions.

Transformative experiences. Dr. Peterson quoted L.A. Paul’s definition of a transformative experience: “...a kind of experience that is both radically new to the agent and irreversibly changes her in a deep and fundamental way, and impacts the way that she lives the rest of her life” (Paul, 2014). Dr. Peterson said he had had a daughter, climbed the peaks of the Alps, and gotten a PhD, and each of these events met this definition of a transformative experience. He suggested that most, if not all, people have had such experiences; marriage, divorce, or caring for someone who is dying all might change one’s life in a deep and fundamental way.

Carel and Kidd (2020) distinguish between two types of transformative experience:

- *Epistemically transformative:* an experience that teaches you something you could not have learned without having that kind of experience. Dr. Peterson observed that no amount of watching war movies would give him the experience of being in combat.
- *Personally transformative:* an experience that changes you in some deep and personally fundamental way. Dr. Peterson noted that becoming a father made him more risk-averse, for example.

Scholars suggest that such experiences complicate the decision-making process. For example, the speaker showed a cartoon in which a person is deciding whether or not to allow a vampire to bite him and is thinking: “I do not know what it will be like to be a vampire until I actually become a vampire.” The concern is that, in regard to possible experiences that may be epistemically transformative, a researcher might not adequately disclose risks and benefits and a participant might not adequately understand them. In reference to personally transformative experiences, there is the possibility that a participant’s values might change through the experience in a way that contradicts the person’s prior preferences. Jacobs (2023) argued that because of the unique aspects of psychedelic-assisted psychotherapy, including acute and long-term effects as well as the long-term shifts to outlooks, values, and priorities that can follow treatment, prospective participants “cannot meet the requirement of understanding that is one of the principal analytic components of informed consent.”

Dr. Peterson opined, however, that the transformation caused by psychedelics differs in degree, not in kind, from other daily experiences. When scrutinized, he suggested, the very notion of a “transformative experience” is rather fuzzy. It is difficult to make generalizable claims about such experiences.

Informed consent. Even granting that psychedelic substances do induce transformative experiences that cannot be predicted, Dr. Peterson held that research participants often provide consent to procedures without a thorough understanding of possible outcomes, and this is not seen as a problem. Even if psychedelic experiences are ineffable, prospective research

participants would not be consenting in an information vacuum. Why should psychedelics research be seen as posing unique problems and held to an exceptional standard?

In conclusion, Dr. Peterson noted that while the problem of transformative experiences may be overstated, psychedelics do pose special risks. These include the suggestibility of subjects, questions around therapeutic touch, and the possibility of adverse psychological events. He also noted that some of the populations for which psychedelics might be beneficial might also have impaired capacity to consent. Nevertheless, there is a good deal of data that can be shared with prospective participants who will not be participating without information on possible risks and benefits.

Panel I Discussion

The search for precedent. Professor Fernandez Lynch introduced the discussion by observing a common thread throughout the presentations: What is or is not exceptional in the context of psychedelics research? As IRBs try to grapple with this, she suggested, they will be looking for examples. What are some helpful analogies?

Dr. Sisti reiterated that psychedelic-assisted treatment is ensemble treatment that has a longitudinal aspect. This, however, is not unique. Psychiatrists routinely prescribe medicine and then ask the patient to come back so they can assess its effects. Dr. Waring agreed, but stressed that this type of treatment magnifies the patient's suggestibility and vulnerability in ways that other prescribed medicines do not. He noted that psychedelic research is exceptional in that it has to address methodological issues inherent to both pharmacology and psychotherapy. As these substances become decriminalized, researchers will be challenged to discover what works in what way and for whom. Data will be needed to guide these decisions.

Mr. Potter observed that few bills being considered by states or local areas incorporate ongoing reporting or infrastructure that might yield needed data, with the exception of a bill being considered in Pennsylvania. He advised DHHS to set up direct communication with state programs and state regulators to learn from their experiences, as well as with first responders and health departments at state and local levels. It is important to get ahead of problems to the extent possible.

Approaches to learning and access. What is the best approach for learning about psychedelics and addressing access issues? Professor Fernandez Lynch wondered to what extent the traditional medical model of the U.S. Food and Drug Administration (FDA) should be applicable or whether some new combination of approaches would be needed.

Dr. Sisti registered a vote for the FDA model, which would expand access sagely within a traditional model. Professor Fernandez Lynch observed that this model would focus on highly medicalized claims with supporting evidence.

Although Dr. Peterson has argued against exceptionalism, he commented that he has doubts about how well the FDA framework would work. He has heard that there is a deep spiritual significance in the practice of psychedelic use; exploring this experience might be almost like doing a research project on going to church. For many, use of psychedelics is embedded in

cultural practices, and their use is not necessarily about attenuating a particular condition in a measurable way.

Mr. Potter argued against any hegemony among the various approaches to learning. The Colorado law is probably the best model, since it integrates decriminalization with the psychedelics-assisted therapy model. It is not wise to try to eliminate legacy markets and all that has been learned through them. As legalization proceeds, multiple market models will exist simultaneously, and it is not clear how the supply side of the market will be regulated.

Dr. Yehuda said she understands that within the framework of state law, Colorado and Oregon are considering legalizing psychedelics research in the context of treatment for a particular psychiatric condition. This is different from the way the population at large may wish to use psychedelics. Is there a case for reimbursing use for people who want the possibility of a spiritual experience but have no medical need for it? How can the existing market be regulated? The price tag for approved psychedelics is likely to be very high with or without therapeutic facilitation of the experience.

There is some pushback against the idea that psychedelic-assisted therapy really is therapy. Some models do not even require facilitators to have college degrees, and no specific diagnosis is required. Another panel member noted that the different models developed by states constitute a “wild west” in which multiple approaches are being established and commercialized.

Dr. Sisti stressed the importance of clear messaging and effective education around the risks and benefits of this type of therapy, as well as ensuring that the right people are steered toward it. The public may misunderstand the possible benefits and may have heard exaggerated claims about what it can do.

Empirical research and variability. In traditional biomedical research, Professor Fernandez Lynch noted, investigators strive to make experimental conditions controlled and uniform. However, in the psychedelics research mindset, setting and the integration process seem to be important but are also highly variable. What are the barriers to conducting rigorous empirical research with this degree of variability?

Dr. Waring said trials for this type of research can be difficult to design and expensive to mount. Patients always expect something from the treatments they pursue, and these expectations are an unavoidable part of many studies, including those involving antidepressants. Patient expectancy is increasingly seen as a contributing factor to therapeutic benefit that merits greater acknowledgement in treatment, as well as its own research focus. Some researchers have proposed supplementing data with trials using different designs (e.g., pragmatic trial designs) that have a broader scope than typical randomized controlled trials (RCTs) and investigate whether treatments given in real-world circumstances have clinically meaningful effects. He suggested that we have a way to go before we understand what can be generalized from the evidence. Most experimental subjects to date have been white people treated in carefully controlled situations. It is important to find out how a more diverse population will respond. Of course, people can and do experiment with these substances on

their own, and it is an open question to what extent these anecdotal experiences should play a role in setting standards.

Another element in variability is the researcher's own experience with psychedelics. Dr. Peterson suggested that researchers who have tried the substance used in the study may have a better sense of risk and might be better at describing possible effects. However, there is a legitimate concern about hype. Does it improve the process if researchers are required to have this experience? Dr. Peterson noted that he is of two minds on the subject.

Dr. Silverman stressed that research is needed because there are so many unanswered questions, and he believes the medical model provides an appropriate way to proceed. In regard to whether researchers should have experience using psychedelics, he noted that personal experience on the part of the researcher is not required in other contexts, such as specific types of surgery. Also, someone who has had a positive experience might be biased in the belief that others should experience similar results.

Dr. Neitzke-Spruill asked where the line should be drawn in explicating all the potential risks. Overdoing it could induce the placebo effect. People who are told they may experience psychosis may be more likely to have deleterious psychological effects than those who are using substances in a Native American church, where expectations are very different.

Dr. Celidwen observed that Native traditions use these substances in a quest for balance and well-being for the planet, and these ontologies have been in place for many generations. In contrast, the medical model focuses on disorders. Professor Fernandez Lynch agreed that existing rules governing biomedicine are narrow and do not address the Indigenous perspective.

Many people are not naïve in regard to psychedelics, Dr. Silverman pointed out, and there is an extensive history of their experiences, though it is primarily anecdotal. Underground treatment providers and users often have developed their own safety protocols. Some provide safe spaces at festivals for people having adverse experiences. The field is not proceeding in an empty room, and the real-world experience of users and underground providers should be taken into account to the extent possible. Also, it is helpful to remember that the population interested in psychedelics is diverse. One subset will not want "those whitecoats" in the room, while more elderly people may feel safer accessing such experiences through the medical system.

Considering the ethical concerns associated with researchers and facilitators in the field, Dr. Sisti recalled that Americans did not pay attention to the Nuremberg code because they believed they had nothing in common with Nazis and did not acknowledge the extent to which systems might encourage different types of behavior. How do you cultivate virtue? More education and mentoring are needed for facilitators, as well as deeper consideration of who is ideal to take part in this work, and licensing or credentialing boards may evolve to field complaints and weed out those not well equipped for the work.

Round robin takeaways. Professor Fernandez Lynch asked each of the panelists final questions: What do you think OHRP needs to know about oversight of psychedelics research as a regulator? What would be the key message you think IRBs need to hear?

- Dr. Waring stressed that supportive post-trip work is essential. IRBs need to understand psychedelics research as drug-assisted psychotherapy.
- Dr. Peterson stressed the importance of taking the potential for bias into account, both on the part of researchers and subjects.
- Mr. Potter urged OHRP and the National Institutes of Health (NIH) to be in ongoing communication with states. Research in states with new legislation relating to psychedelics probably will be in place far earlier than whatever happens with FDA oversight.
- Dr. Sisti stressed that qualitative research is as legitimate as other forms of research and complements other types of knowledge.

Session II: Considering Practical Aspects of Psychedelics Research

- *Moderator:* Benjamin C. Silverman, MD, Senior IRB Chair, Mass General Brigham; Director of Ethics, McLean Institute for Technology in Psychiatry, McLean Hospital; Instructor in Psychiatry and Faculty Member in the Center for Bioethics, Harvard Medical School

Session II Introduction

- Benjamin Silverman

Dr. Silverman explained that Session II would focus on the practical aspects of conducting psychedelics research. These clearly overlap with legal and ethical concerns, some of which were presented in Section I. The previous session raised important ethical issues, highlighted conflicts of interest in markets, and stressed the possible vulnerability and suggestibility of subjects, as well as the need for appropriate boundaries between subjects and facilitators. Among the challenges that require further consideration are approaches to obtaining informed consent and equitable access to trials, including making opportunities available to underrepresented populations.

What Are the Challenges in Designing Scientifically Sound Clinical Trials for Examining the Effects of Psychedelics?

- Rachel Yehuda, PhD, Professor of Psychiatry and Neuroscience, Director, Center for Psychedelic Psychotherapy and Trauma Research, Icahn School of Medicine at Mount Sinai; Director of Mental Health, James J. Peters Veterans Affairs Medical Center

Dr. Yehuda focused her remarks on several of the major challenges that must be addressed in psychedelics research. These include issues relating to appropriate comparison groups for clinical trials, participant-related considerations such as whom to include and exclude, and the role of support for the participant (including psychotherapy).

Comparison groups. Ideally, in controlled trials, investigators and participants are blinded in regard to which groups are receiving placebos and which are receiving the product being tested. In the case of psychedelics, however, it is very clear to most people that they have been given a psychedelic. Although blinding and placebo controls are considered foundational in randomized clinical trials, Dr. Yehuda suggested that this challenge is not necessarily a deal breaker. While blinding is helpful in minimizing investigator and subject bias, it is not always

possible. For example, blinding of patients and therapists usually is not possible in psychotherapy trials, which still are considered valid. Perhaps it would be helpful to consider psychedelics research more like psychotherapy trials than other clinical trials.

Several alternative approaches are possible. It would be helpful to compare psychedelics therapy to existing standards of care for a particular condition, including medication. Another approach would be the use of active placebos that make you feel something. Dr. Yehuda stressed that this type of research is not simply about the drug but about the whole process by which the drug is introduced and its effects are integrated. Promising topics for research include comparisons of responders and nonresponders, dose-optimization studies, and examinations of issues related to clinical practice once such drugs are approved.

Participant-related considerations. Dr. Yehuda described the unprecedented interest in psychedelics research; people contact her center frequently despite the complete lack of advertising. Unfortunately, many of these prospective subjects are ineligible for studies based on psychiatric or medical exclusions, and a disproportionate number of these individuals are people of color. She added that there is no way to design an informed consent process that addresses everything that could happen, and lengthy informed consent documents make people fearful.

The abyss between requirements for subject participation in clinical trials and the issues faced by people encountered in actual medical practice must be narrowed. Dr. Yehuda considers this a major ethical issue. In the “real world,” people present with comorbid conditions, trauma, suicidality, personality disorders, and other features that are difficult to treat, yet psychedelics investigators are supposed to seek “pure” participants who do not have these conditions. This may result in studying the wrong people.

The role of support and psychotherapy. Dr. Yehuda pointed to the danger of resorting to a reductionist pharmacological model that does not view psychedelics as part of a process designed to offer a new psychological/existential/spiritual perspective. Preparation before, facilitation during, and integration after a session appear critical (though this working assumption remains to be conclusively proven or disproven). There is much to be studied. Examples include the appropriate setting for psychedelic experiences, the most effective psychotherapeutic approaches, the number and frequency of integration sessions, and the need for future booster sessions.

Dr. Yehuda expressed concern that practical and economic factors might result in minimizing the role of psychotherapy or that the need to integrate psychotherapy and drug administration might complicate FDA approval. Already, more attention is being paid to biological receptors for drugs and less to essential supports. Dr. Yehuda also stressed the importance of training, education, and credentialing for people who act as guides or facilitators for these experiences. At the same time, she observed that facilitators are already charging so much that it is heartbreaking.

In closing, Dr. Yehuda raised several questions that she believes merit further discussion:

- How can design challenges be overcome, and what creative clinical trial designs might be useful? (FDA participates in designing studies that receive breakthrough status—do we need to second guess these strategies?)
- What are the foundational aspects of clinical trials, and do some of the classic approaches to clinical trials need to be reexamined or modified?
- What are the most salient questions to be asking?
- Should we be distinguishing between what may be necessary for drug development and approval as opposed to exploring the utility of available compounds in clinical practice?
- How can we move forward in understanding the role of psychotherapy and facilitation?
- Should personal experience on the part of the investigator be encouraged? Will it help clarify therapeutic potential? Will it introduce bias?

What Are the Challenges with Evaluating and Minimizing the Risks of Research Involving Psychedelics?

- Natalie Gukasyan, MD, Assistant Professor, Columbia University School of Medicine

Dr. Gukasyan discussed the known risks of psychedelics and mitigation strategies to reduce their effects, issues relating to informed consent, and challenges and opportunities involving adverse event reporting. She began by contrasting classical psychedelics (5-HT_{2a} agonists or partial agonists) such as psilocybin, LSD, mescaline, and DMT with nonclassical psychedelics such as MDMA, ketamine, salvia, and ibogaine. She observed that classic psychedelics and MDMA have been shown to be well tolerated in properly screened and well-supported individuals in research settings. Standards and appropriate aftercare have resulted in reduced risk.

Risks. However, not all psychedelics are created equal. Risks may be drug-, dose-, and frequency-dependent. Psychological or psychiatric risks that subjects could experience include:

- Precipitation of mania or psychosis in vulnerable individuals.
- Exacerbation of mental health issues, including suicidal ideation.
- Hallucinogen persisting perceptual disorder (HPPD), which is an understudied condition about which little is known about who is subject to it or how to treat it.
- Challenging experiences, which are not necessarily associated with poor outcomes and could be worked through. These could, however, include behavioral emergencies that carry the risk of harm to oneself or others.
- Possible risk of abuse in vulnerable populations, though classic psychedelics have been shown to have relatively low abuse liability. Less data are available on nonclassic psychedelics.

Somatic or medical risks may be encountered as well and could include:

- Transient hypertension/tachycardia or other cardiovascular events
- Nausea/vomiting
- Headache
- Medication interactions

- Valvular heart disease.

Screening. Screening in research settings may take 2 days to complete. A full psychiatric assessment is appropriate—not simply asking if someone in the family has schizophrenia. This assessment would include family history as well as personal psychiatric history, a physical exam and history, and electrocardiogram (EKG) and bloodwork, including ensuring normal liver and kidney function.

Dr. Gukasyan observed that the following conditions commonly result in individuals being excluded from trials involving the use of psychedelics, though this list is simply historical rather than a suggestion of what *should* be standard of care:

- Cardiovascular conditions, such as uncontrolled hypertension.
- Epilepsy.
- Hepatic impairment.
- Use of contraindicated medications, such as lithium and antidepressants. Dr. Gukasyan noted that half of subjects taking lithium had serious seizures in a Hopkins study (Nayak et al., 2021). For antidepressants, there is recent evidence that tapering medications might be sufficient.
- Personal history of psychotic or bipolar disorder or a first degree relative with such a condition.
- Clinically significant personality vulnerabilities.
- Acute risk of suicide. Although some researchers want to target this condition for treatment, increased safeguards would be needed.

Mitigating risks. Dr. Gukasyan pointed out that risk mitigation begins well before drug administration and continues afterward. Consent and preparation include ensuring that the participant understands the range of potential drug effects and is prepared for the possibility of a challenging experience. It also includes explaining how monitors would respond to psychological distress. Dr. Gukasyan suggests a dry run in which the person lies down with eye shades in the presence of a monitor. She also stressed that a good rapport between monitors and participants is essential.

During drug administration, vital signs should be monitored as appropriate, and medication that might be needed in case of emergency should be available. It is good practice to have an MD on call and to make a video recording of the session in case there is disagreement between the monitor and the subject about what happened in the session. Verbal reassurance and deescalation may help the subject deal with a challenging experience.

Following the session, facilitators should provide a flexible number of sessions as needed to help the subject process whatever happened in a positive way. Mitigating risk after treatment could include addressing suicidal ideation, symptoms of HPPD, use of psychedelics and other drugs outside of the research setting, or symptoms of mental health problems such as mania or psychosis.

The speaker stressed the need to harmonize the collection of acute and subacute drug effects. Adverse events (undesirable patient experiences associated with the use of a medical product)

should be reported. She observed that tools like MedRA, a standard form used in FDA-monitored drug trials, may be inadequate to capture the scope of effects for psychedelic substances.

Exploitation or Inclusion? Exploring the Ethical Obligation and the Unique Challenges with Including Black and Brown Populations in Psychedelics Research

- Daron Smith, PhD, PA-C, DFAAPA, Associate Program Director, Research and Scholarship, MEDEX; Co-Director, Center for Novel Therapeutics in Addiction Therapy

Dr. Smith observed that psychedelic-assisted medicine is an emerging field. For example, the Multidisciplinary Association for Psychedelic Studies (MAPS) currently is conducting [Phase 3 trials](#) in the U.S. and Canada to determine the effectiveness of MDMA for the treatment of PTSD. FDA has characterized the use of MDMA in this context as a breakthrough treatment. However, study participants to date are mostly white and of high economic status. Very few trials have included people of color, and even fewer have intentionally recruited them as their subjects. The question remains: Is this same effect true for marginalized individuals and groups?

Racism and racial trauma. Anti-black racism can and does trigger racial trauma, defined as cumulative psychological injury caused by hate or fear of individuals due to their ethnicity or race that overwhelms the individual's ability to cope (Williams et al., 2021). African Americans live with higher rates of PTSD due to direct and indirect exposure to trauma. The racist past and contemporary reality of ongoing mistreatment of black people can trigger PTSD-like symptomology due to chronic hyperarousal of the nervous system. Racial stressors include microaggressions, violence, police profiling, race-based mass shootings, systemic racism, and discrimination. However, barriers remain to facilitating access to MDMA as a promising source of symptom relief for this population.

Dr. Smith observed that the “War on Drugs,” initiated in the Nixon era, was closely associated with opposition to the civil rights movement and resistance to the Vietnam War. The stigma associated with psychedelics halted research until the 1990s, but it continues to influence drug policies today. Racial minorities have experienced disproportionate criminal penalties for drug use, and race-based inequities exist in prescriptions and treatments using pharmacotherapies. Racist assumptions result in habitual overdiagnosis of psychotic disorders among people of color (which can make them ineligible for some trials of psychedelics), while anxiety, depression, and PTSD are chronically *underdiagnosed*.

Psychedelic-assisted therapy could be beneficial for BIPOC who are struggling with race-based stress and trauma. Williams et al. (2021) found significant reductions in depression, anxiety, and stress following naturalistic use of psychedelics for racial trauma, and a prospective study in Jamaica will test the replicability of this result. However, there is concern that facilitators who are untrained in racial trauma might create even greater trauma by minimizing and misunderstanding its effects. White physicians have been shown to underprescribe pain medications for BIPOC due to the racist belief that this population experiences less pain. Dr. Smith stressed the need for providers and facilitators to unpack their own biases before they

attempt to facilitate healing. Training in intersectional cultural humility and implicit bias may help in this process (Buchanan et al., 2020).

What is needed now. Dr. Smith stressed the need to hire and train more therapists of color using a culturally informed approach and antioppression lens to conceptualize clients' trauma. BIPOC who undertake this work may experience better results; multiple studies have shown that people exhibit greater empathetic resonance to individuals with a similar skin color. Many BIPOC therapists currently are working underground, and some of them are doing good work that may never be taken seriously. Dr. Smith underscored the importance of culturally sensitive facilitators in an industry in which many mental health practitioners harbor unexamined implicit biases but remain gatekeepers for diagnosis and access to treatment.

Dr. Smith pointed to many encouraging developments. MAPS has the opportunity to create a more positive and inclusive clinical pathway where BIPOC members can thrive in psychedelics-focused programs. The California Institute of Integral Studies (CIIS) operates a few academic programs dedicated to educating the next generation of psychedelics practitioners via the development of the [Certificate in Psychedelic-Assisted Therapies and Research \(CPTR\)](#) program, and this could benefit BIPOC therapists. The Alma Institute in Oregon is developing [culturally responsive curricula](#) for facilitators of psychedelics research using psilocybin. A number of psychedelic clinics are oriented to racial justice (for example, the Sage Institute, the Sound Mind Center, the Behavioral Wellness Clinic, and the Sana Healing Collective).

Dr. Smith urged academic centers at predominantly white institutions with newly established psychedelics programs to reach out to Historically Black Colleges and Universities (HBCUs) to initiate mutually beneficial cooperative programs. He also observed that, to date, no universities are offering psychology- or medicine-based programs that offer a specialization in therapy for racial trauma. More creative suggestions are necessary to speed up timelines for training programs in psychedelic-assisted therapy. Finally, Dr. Smith stressed that sites that already are using culturally informed therapeutic practices need to be bolstered and funded, while collaborations among the psychedelics treatment community, predominantly white institutions, and HBCUs are critical to increase the accessibility of psychedelic-assisted therapy for underserved populations.

Addressing the Challenges with Conducting Psychedelics Research Involving Criminal Justice-Involved Populations

- Logan Neitzke-Spruill, PhD, Postdoctoral Associate, Center for Medical Ethics and Health Policy, Baylor College of Medicine

Dr. Neitzke-Spruill said that while he has observed an increasing number of applications to conduct psychedelics research with justice-involved populations, often coupled with the suggestion that psychedelic-assisted therapy might help reform convicted criminals, he does not believe psychedelics should be cast as a universal cure for whatever ails us individually or as a society. The fact that racism clearly is evidenced in the criminal justice system adds to concerns about conducting such research on a vulnerable population in a prison setting.

The Federal Policy for the Protection of Human Subjects (the Common Rule) provides guidelines for such research with prisoners under Subpart C. IRBs are charged with ensuring that such research is “commensurate with risks that would be accepted by non-prisoner volunteers” (45 Code of Federal Regulations [CFR] §46.305 [3]). The Rule does permit “research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject...” (§46.306 [2] iv).

Claims and evidence. Interest in psychedelics as a treatment for criminal behavior became of interest in the mid-20th century. However, evidence for such a claim is sparse. Some experiments in Canada introduced psychedelics as correctional tools with a population of nonconsenting individuals, with no demonstrated positive results. Statistical results have been positive in some contemporary studies, but the use of psychedelics occurred prior to subjects’ involvement with the criminal justice system, so the idea that their use might attenuate criminal behavior clearly is not supported. Not only is evidence to support the use of psychedelics in criminal justice populations scarce and severely limited in scope, but the idea that psychedelics might deter criminal activity lacks any clear connection to theories of crime. Social influences on criminal behavior are not taken into account, and there is very little evidence that mental health counseling can deter crime.

Concerns. Dr. Neitzke-Spruill also highlighted concerns related to the prison setting in which the treatment would be administered. Prisons in themselves may be psychologically damaging and are not likely to provide adequate support for vulnerable individuals who enter hypervulnerable states as a result of psychedelics use. Many prisons use private contractors to provide various services, including administration, and they are known to cut corners (in medical care as well as other areas). Why introduce research that calls for special supports if it is to be conducted ethically to institutions that already are underfunded? In addition, even if prisoners had a positive experience, they would have limited capacity to enact changes while incarcerated, and the same barriers to reentry that contribute to recidivism are likely to hinder integration.

Although these factors suggest that benefits of psychedelic-assisted research would be limited and risks would be elevated with incarcerated participants, Dr. Neitzke-Spruill suggested that prospective research might focus on psychedelic use with formerly incarcerated individuals. However, reentry programs are chronically underfunded, so it is unclear whether this would be feasible. Given the importance of social conditions in securing positive outcomes, Dr. Neitzke-Spruill pointed to the need for more qualitative assessment of psychedelic therapies.

Panel II Discussion

Toward diversity. Dr. Silverman observed that the presentations clearly demonstrate that many questions remain to be answered regarding practical aspects of conducting psychedelics research. One of the biggest issues is around generalizability, given the fact that most research to date has involved comparatively well-off white men. A research paper was published recently in this subject area in which 86 percent of subjects in the study arm treated with psilocybin were white, and 51 percent had a salary over \$100,000 (Raison et al., 2023). Dr. Silverman asked a broad question: How do we fix this? We have a huge problem with lack of

diversity in all clinical trials, but it is particularly striking in psychedelics research and may be especially challenging to address.

Reminding attendees of the legacy of unethical research in which people of color have been unwilling subjects, Dr. Smith stressed the importance of recruiting researchers who are people of color. He noted that although the war on drugs scared the hell out of black and brown people and they are understandably skittish of government-sponsored programs, he appreciates the fact that NIH has some programs in place to help junior researchers. He suggested that researchers who want to recruit BIPOC as subjects would do well to bear in mind that this population often has fewer resources and may need support for transportation and other research-related expenses. Paying subjects for lost work time is also appropriate. Finally, he encouraged researchers to openly acknowledge the history of research abuse with prospective black and brown subjects.

Dr. Gukasyan agreed that research teams should look like the community. When this is not the case, they should be prepared for a long process of getting to know the community and vice versa. She also noted that there may be a fine line between outreach and coercion. Dr. Smith suggested that conversations with BIPOC religious leaders often are helpful in bridging the gap between researchers and communities.

Despite the fact that equitable subject selection is required by federal research regulations and IRBs as one of the criteria for study approval, Dr. Silverman observed that the recent study cited earlier in this discussion was obviously unbalanced. Getting information from investigators on how, specifically, they plan to recruit diverse subjects is much easier said than done. This should occur at the time of initial review and approval, and the IRB should hold investigators accountable to their plan. If the IRB learns of inequitable subject selection during the course of the study, what should the IRB do when it becomes aware of the fact? Should the study be stopped?

Panel members did not respond to the question directly but, instead, offered additional observations on recruitment strategies. Dr. Smith suggested developing a national registry of prospective BIPOC research participants that would be one source of diverse subjects. He said that some states are trying to do this, including North Carolina.

Dr. Gukasyan stressed the need for skilled facilitators who can build rapport with subjects, which is probably, in part, a trainable quality. She noted that her team has occasionally had to exclude people whom they find are unable to create such a rapport.

Professor Fernandez Lynch cautioned that when we discuss clinical trial diversity, we need to be specific about why it matters. In regard to inclusion of racial/ethnic minorities in this research, the rationale for inclusion is not about biologic differences but, rather, about differences that might stem from different life experiences and cultural perspectives, which are probably especially relevant for psychedelic outcomes.

Criteria for exclusion. Dr. Silverman invited the panel to consider the opposite problem from equitable inclusion—exclusion and protection. Being clear about exclusion criteria for the sake

of adequate participant protection is especially important in psychological research. He asked whether it is necessary to expand or minimize exclusion criteria as psychedelics become more accessible and research moves forward.

Dr. Smith said the reason for excluding a participant should be a reasonable concern about the person's safety. He recently had to turn someone away who was one symptom short of diagnostic criteria that vary constantly, and he felt that was too strict. Real-world studies are needed. Perhaps, he suggested, we need studies to determine whether some common exclusions really should be exclusions. He added that he would like to offer MDMA-assisted therapy to clinicians in training. He believes it might help them push the boundaries of a diagnosis or respond to a particular situation.

A distinct issue with psychedelics research is that, unlike other therapies, people want to use psychedelic-assisted approaches for a wide range of reasons that do not fit a particular label. There is a big gap between the medical world and the actual world, Dr. Smith continued. Should a person have to have a psychiatric condition to access this therapy? He suggested anyone should be able to, so long as there are some well-thought-out guidelines.

Dr. Neitzke-Spruill also argued for a more inclusive approach. He commented that the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) is often too restrictive to serve as a source of exclusionary criteria. Common symptoms and difficulties would be a better approach to screening and also would help increase diversity. Dr. Smith agreed, adding that excluding people on the basis of DSM diagnostic criteria is problematic in other types of trials. He noted that there are few studies on how to treat people who do not meet criteria for some specific condition.

Dr. Gukasyan observed that people often are excluded from studies because they are not sick enough. Sometimes grant funders have specific criteria in mind that must be honored by the awardee. The problem could be addressed by making sure that research settings are not the only place where treatment can be accessed. She also noted that testing drugs with healthy people can be met with pushback and that she understands this position; the therapy is resource-intensive and might best be offered to people who are suffering.

Risk of substance use disorder. Dr. Silverman asked a question raised by a member of the audience, who observed that one of the fears around medicalizing the use of psychedelics is that it will simply be a way for some people to get drugs legally. There could be some risk of misuse or potential abuse liability. Perhaps people with substance use disorders will enroll and seek more experiences after the trial, or others without substance use disorders might develop one. How might these concerns be factored into study design and content?

Dr. Gukasyan commented that psychedelic-assisted therapy is being studied for the treatment of substance use disorders. People who are active substance users may not want to enroll in a trial based on a medical model, however. Why would anyone go to the effort of participating in a trial when they can obtain and use drugs on their own relatively cheaply?

Mr. Potter observed that for some people, use of certain substances is a deeply embedded part of their cosmology, values, and spiritual path. There is a disconnect between the thinking behind the Controlled Substances Act (CSA) and the openness of the FDA to therapeutic use of psychedelics. People who participate in research might find a substance useful and want access to it. There is no good reason for a medical use monopoly. Dr. Sanders agreed, noting that people have been trying to help themselves by using psychedelic substances for a very long time.

Dr. Silverman appreciated these points and acknowledged that people are not particularly worried about the development of new substance use disorders as a result of enrollment in a psychedelics research study. He noted, however, that legalization and FDA approval add a sense of legitimacy to a substance and may result in more people being more apt to use it. There are data that youth now perceive cannabis as less harmful and may experience a slightly increased risk of psychosis, especially in particularly vulnerable groups (Ladegard et al., 2020). Decreased perception of harm that comes with legalization and FDA approval of psychedelics may pose risks to more vulnerable populations.

Dr. Smith suggested that people who have experienced psychedelics in the context of a clinical trial are probably less likely to think of it as something they want to do on their own. If the drug is given in a therapeutic context and participants feel they “got to the other side” of whatever they were facing, there may be no need to repeat the experience. People who try the drugs for self-exploration are more likely to do so again and again.

Round robin takeaways. In closing, Dr. Silverman invited panelists to offer take-home messages to OHRP or to investigators. Remarks were as follows:

- Dr. Yehuda observed that we need a lot of conversations around how to make trials more generalizable and informative in the contexts in which findings will be used.
- Dr. Gukasyan stressed that trial designs to date should not necessarily be the standard going forward. Study protocols would benefit from allowing for more flexibility (for example, in the amount of support offered to the subject before and after treatment).
- Dr. Smith proposed making sure that 25 percent of study participants and staff are people of color.
- Dr. Neitzke-Spruill said we need to be more creative in measures of success and what we accept as evidence rather than focusing on the search for biomarkers. Treatment may not meet a threshold in a particular survey instrument but still be valuable to the participant.

Session III: Safeguarding Public Trust; Preventing Another Psychedelics Bubble

- *Moderator:* R. Cameron Wolf, PhD, Senior Advisor, Center for Substance Abuse Prevention/Office of Prevention Innovation, Substance Abuse and Mental Health Services Administration

Session III Introduction

- R. Cameron Wolf

Dr. Wolf observed that most of his career has been focused on HIV and scaling up, both domestically and internationally, programs for prevention, care, and treatment, particularly targeted towards key populations and vulnerable populations. He pointed to parallels between that work and the current state of psychedelics. There was so much desperation and so many people were at death's door and really looking for answers, looking for treatments, and looking for life-saving options, and they were willing to try anything, regardless of safety. Once more effective medications arrived on the scene beginning in the mid-1990s, Dr. Wolf noted, the driving issue changed to one of access. In 1996, there were effective combination treatments with protease inhibitors coming out that seemed to bring people back from the dead. As these effective treatments arrived, however, issues of equitable access also arose—how to tailor and target programs to the most vulnerable individuals. Dr. Wolf noted that his experience in this era colors this discussion of public safety for him and highlights the key word, “trust.”

Remarks by Rosalind Watts, PhD

- Founder, [ACER Integration](#)

Dr. Watts led long-term trials at the Imperial College of London to test the efficacy of psychedelics as a treatment for depression. Some subjects may have experienced a journey with depression that lasted as long as seven or eight years. A lucky participant sometimes had a sudden and dramatic experience with the drug and never experienced depression again. Much more common were instances in which subjects experienced a deeper sense of connection to self and universe, and then the depression began to return. Studies often stop measuring results at six months, which is about when long-term studies have found the depression coming back.

The narrative around psychedelics therapy needs to shift, Dr. Watts noted, and more care should be given to the necessity of aftercare. Addiction issues need to be addressed. Focus is needed on preparing the community structure that is needed to help people integrate their experiences over time. Dr. Watts stressed that a major issue is that disconnection from the community is often part of the reason that people are unwell and suffering, and the rooted problems that led to depression need to be addressed within a cultural container.

Dr. Watts observed that the period of time following a psychedelic experience is a time of tenderness and risk in which a window of opportunity opens. If there is no investment in aftercare and community support, individuals may be overwhelmed by stressors and feel a sense of abandonment. They may have ended a job or relationship in the wake of their experience and feel ungrounded. Huge numbers of people may one day be using MDMA; to prepare, she stressed, we need to invest in community structures to provide essential support.

Remarks by Juliana Mercer

- United States Marine Corps Veteran, Federal Advocate in Promoting Safe Access for Veterans to MDMA and Psychedelics for the Treatment of PTSD

Ms. Mercer provided information on her personal background to explain her passion around the healing potential of psychedelics for veterans with PTSD. She graduated from Marine Corps boot camp the week before 9/11 and spent 10 years in active duty in Iraq and Afghanistan. She saw the true cost of war every day during her time at the Wounded Warrior Battalion. On

returning home, she faced a losing battle against PTSD, as many veterans do. She noted that the veteran suicide rate among veterans with traumatic brain injury has increased tenfold since 2006 (Howard et al., 2023).

Ms. Mercer said she knew she needed help. She had a psychedelic experience through a nonprofit organization, [Heroic Hearts Project](#), that allowed her to shed 20 years of collected trauma and grief. In the mirror, she saw a woman with a joyful face that she had not seen for a very long time. She became active in [Healing Breakthrough](#), which encourages safe and legal access to promising therapies available through the Veterans Administration to those who need them.

Veterans are helping to prevent another psychedelic bubble and are positioned to be influential advocates for the acceptance of these modalities. Their advocacy has opened the doors to bipartisan support as they educate legislators. Ms. Mercer's advocacy team at Healing Breakthrough has met with over 300 legislators and policy makers and found overwhelming support. The Veterans Administration needs to prepare to take MDMA-assisted therapy to scale. Its work can help establish standards for the safe and effective use of this treatment approach, changing the conversation and paving the way for other breakthrough therapies.

Remarks by Laura Sanders, PhD

- Senior Writer, *Science News*

Dr. Sanders spent 15 years as a reporter, writing about subjects such as early childhood, consciousness, and brain changes caused by COVID 19. She works for *Science News* magazine, a nonprofit publication that appears in print every other week, online and on various social media platforms. Its mission is to tell people what is going on in the world of science, in language they can understand. She has been watching the boom in psychedelics research with interest.

A news story worth reading, Dr. Sanders said, must be novel, interesting, and/or important. Usually, a good story has at least one of these traits and sometimes has all three. The reader is best served by being given the whole story. Details and necessary caveats are important so that the reader understands what the data say and what they cannot yet tell us. Examples of qualified headlines presented by Dr. Sanders include:

- Psychedelics may improve mental health by getting inside nerve cells.
- Psilocybin may help treat depression, a small study finds.

The writer must consider whose voices ought to be included. Often, it is helpful to seek information from people not directly involved in the particular study of interest, such as trial design experts, people in Indigenous communities, study volunteers, or others who have used the research drug.

Other considerations for a careful writer include:

- *Balancing anecdotes and data.* Anecdotes based on someone's experience can make the story real, but they have to be balanced with what the data show.

- *Word choices.* Psychedelic experiences can be described with loaded words such as “trip,” “mystical experience,” or “ego dissolving.” The writer has to balance what those words imply and what we know. People can react strongly to connotations words have for them. For example, Dr. Sanders used the word “hallucinogen” in a story and an angry reader wrote a letter saying the word was stigmatizing. It is always important to think about who is hearing the words chosen and what they will take away from them.
- *When not to cover research.* Writers need to consider whether a subject needs to be elevated at a particular time. There may be no right or wrong answer, but there are always choices to be made, depending on the goal. It may be necessary to leave something out or even kill the story.

Remarks by Yuria Celidwen, PhD

- Department of Psychology and Othering and Belonging Institute, University of California, Berkeley

Dr. Celidwen observed that she was speaking on unceded land originally cared for by the Piscataway tribe and wishes she had a way to ask for their permission to do so.

The speaker began by highlighting concerns of Indigenous people related to Western use of psychedelics that they, themselves, have traditionally considered sacred and used in a ceremonial context. These concerns include violation of their rights to their tangible and intangible heritage, lack of recognition, and exclusionary practices in research and therapeutics by Western, Educated, Industrialized, Rich and Democratic (WEIRD) investigators and therapists. In response, a group consensus process led by globally representative Indigenous peoples has developed guidelines related to psychedelics and engaged in formal scholarship and dialogue (Celidwen et al., 2023).

The use of these substances is expected to grow as cities and states continue to legalize their use or decriminalize it. Yet, although there were 367 registered studies of medicines considered sacred for Indigenous peoples in March 2022, and there are more than 50 million people using these medicines in the U.S. alone (Phelps, 2017), there is little or no evidence that findings or benefits from commercial use are being shared with Indigenous peoples, who make up 19% of the most extreme poor worldwide and have as many as 20 years less life expectancy.

Dr. Celidwen pointed to the disparity in payment between WEIRD and Indigenous facilitators of psychedelics-assisted treatment. While WEIRD facilitators at retreat centers average earnings of \$10,500, Indigenous facilitators practicing in their communities of origin may receive only \$2 (Celidwen, 2021; Leonhardt, 2020). Yet, Indigenous people have much to share, given a respectful collaborative framework in which to do so. She challenged WEIRD research institutions, industry, and the private sector to dissolve systems based on colonizing and imperialist practices and instead reach out to people in Indigenous lineage holders to bridge best practices that can share benefits to the largest plurality of communities.

Indigenous principles vs. colonial practices. Dr. Celidwen contrasted Indigenous principles with concrete problems introduced by colonial practices. While Indigenous principles call for reverence for Mother Earth, current problems include therapies with high carbon footprints and

other harmful practices. Possible solutions include therapies based on Indigenous wisdom that reorient attitudes toward better relationships with humans, other-than-humans, and Mother Earth.

Indigenous principles also include *respect*, including respect for Indigenous ways of knowing and being. Current practices, however, emphasize extraction and fail to adequately reference Indigenous traditions (for example, the use of psychedelics in medicines, rituals, and ceremonies). Respect demands proper acknowledgement of Indigenous traditions.

A third principle is *responsibility for use, benefits, and harms*. However, colonial practices have included exploitation, dissemination, capitalization, and promotion of appropriated Indigenous medicines. Substance users also frequently promote well-being in non-Indigenous people without considering access to healthcare for Indigenous populations. Dr. Celidwen called for accountability for perpetuating harmful practices.

Dr. Celidwen cited a number of Western institutions and projects that are harming Indigenous communities and their traditions by dividing communities locally in the fight for funding, pushing for the implementation of projects that adopt medicines not traditionally their own in order to meet Western demand, overforaging, psychedelic tourism and consumerism, and other concerns.

Some other research institutions are seeking to move toward more ethical practices in which Indigenous wisdom is honored and Indigenous peoples share in benefits that accrue from psychedelics research and commercial use. Because Westerners have so frequently broken treaties and betrayed trust, these exploratory conversations will take time and patience. Dr. Celidwen stressed that although many institutions are starting to reach out, the process will need to proceed slowly and respectfully to address the many complexities involved.

Panel III Discussion

Risks and benefits. Dr. Wolf observed that a key point emerging from the session discussion is that psychedelics therapy does not offer a magic bullet. Some people show potential gains, while others are declining or getting worse over time. How can balance between risks and potential benefits best be conveyed?

Ms. Mercer said that for many veterans, the risks of psychedelic therapy are less significant than those of everyday life. Because use of psychedelic drugs that may be helpful has been criminalized, some veterans go outside the country on their own in search of healing. It is important to communicate challenges and share information about what works. For the most part, however, veterans with PTSD have had good results. Those who want to pursue this route should have a legal way to do so and be connected with a coach or therapist who can help them with the hard work of integration, thus expanding veterans' access to trauma-informed care.

Dr. Watts also stressed the importance of integration, carefully tailoring and targeting truthful messages about risks and benefits. Based on the hype, some people expect one session to be a powerful life-changing experience; if it isn't, they think something is wrong. Messaging needs to be more nuanced and to stress the importance of the therapeutic work the person will be

doing with the therapist, including preparation and integration. The experience of taking the psychedelic substance should be viewed as part of an ongoing and iterative journey. This approach will reduce the risk of deep disappointment if someone isn't immediately in remission from symptoms. Companies that stand to make profits if the substances are legalized need to invest in community engagement, support, and infrastructure development.

Dr. Sanders noted that risks and benefits may be different for each person. Veterans who are coping with PTSD and may be suicidal are a very different population from those with purely recreational interests. Writers need to be up front and candid about what we do and do not know. She noted that crafting headlines that are interesting but do not mislead the reader is a very hard job and sometimes requires many revision cycles.

Dr. Celidwen stressed the opportunity to build bridges that ensure belonging for all communities, including those who have been marginalized, especially the Indigenous peoples who have long and sacred histories working with these substances. Their voices must be present in the conversation. Western society has a reckoning to pay for its cultural blindness. Trust must be rebuilt, and trust cannot be rebuilt without reparation and respect.

Community-based approaches. Dr. Wolf perceived from the speakers a need for a continuum of care that is capable of nurturing people who have received psychedelics therapy. He challenged panelists to envision what community-led, community-based approaches to psychedelics research might look like.

Dr. Watts suggested that members of a community are best suited to clarify their own needs and sources of support. Peer support is often particularly effective, especially when people have similar problems, lived experiences, and goals related to their use of psychedelics. Some people have a “buddy” with whom they are doing a journey, and that is often helpful and protective. Indigenous ideals, stewardship, community service, and relationship building all should be incorporated in the experience.

Dr. Celidwen commented on the need to move from a medical model for psychedelic use to a larger model centered in planetary well-being, not only for the individual but for the larger community. Context is important. A land-based approach is often helpful for Indigenous communities.

Ms. Mercer recognized that no one size fits all—either indigenous or medical. It is best to have conversations with people about what is suitable and comfortable for them and what will help them get the care they need.

Round robin takeaways. Dr. Wolf commented that the conversation on this subject is just a beginning and invited each panelist to offer a final take-home message.

- Dr. Celidwen stressed that reverence for Mother Earth comes first. There is no human health without planetary health.
- Ms. Mercer observed that these modalities are here, and we are their stewards. It is up to us to see that development goes in the right direction.

- Dr. Sanders stressed that words have tremendous power, and we need to think carefully about what words we choose.
- Dr. Watts reinforced Dr. Celidwen’s emphasis on the importance of reparations to Indigenous peoples.

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SPEAKER BIOGRAPHIES

Session I



Holly Fernandez Lynch, J.D., M.Be. (Moderator)

Assistant Professor of Medical Ethics and Law, University of Pennsylvania

Holly Fernandez Lynch is Assistant Professor of Medical Ethics and Law at the University of Pennsylvania. She pursues conceptual and empirical scholarship regarding clinical research ethics and regulation, access to investigational medicines outside clinical trials, and FDA pharmaceutical policy. She is founder and co-chair of the Consortium to Advance Effective Research Ethics Oversight (www.AEREO.org), board member of Public Responsibility in Medicine & Research (PRIM&R) and the American Society for Law, Medicine, and Ethics, an elected fellow of the Hastings Center, and a National Academy of Medicine Emerging Leader in Health and Medicine. She served as a member of the Secretary's Advisory Committee on Human Research Protection (SACHRP) from 2014 to 2019. Professor Fernandez Lynch has previously worked as an attorney in private practice, bioethicist serving NIH's Division of AIDS, analyst with President Obama's Commission for the Study of Bioethical Issues, and executive director of Harvard Law School's bioethics and health law research program.



Duff Waring, LL.B., Ph.D.

Professor, Department of Philosophy, York University

Duff R. Waring is a philosopher/lawyer who has specialized in mental health law, psychiatric patient advocacy, bioethics, and philosophy of psychiatry. His research has focused on the ethics and praxis of psychotherapy. He is a member of the Law Society of Ontario and is currently a full professor in the Department of Philosophy at York University.



Noah Potter, J.D.

Legal Market Strategies

Noah Potter is a New York City-based attorney and psychedelic sector consultant. In the early 1990s, as an undergraduate political science student, he became an ibogaine legalization advocate and in that context analyzed the relationship between substance abuse prevention and treatment in federal policy priorities. He is chair emeritus of the New York City Bar Association's Committee on Drugs and the Law. In 2010 he articulated the concept of psychedelic law when he created "The New Amsterdam Psychedelic Law Blog". In 2018, he guided the Decriminalize Denver campaign in obtaining board of elections approval of that city's psilocybin decriminalization ballot initiative, which, in 2019, launched a wave of state and local psychedelic law reform around the United States. In 2020, he began briefing New York State and New York City elected officials on psychedelic policy reforms options. His 22 years as a commercial litigator inform his perspective on psychedelic markets.



Dominic Sisti, Ph.D.

Associate Professor of Medical Ethics & Health Policy, Department of Medical Ethics & Health Policy, Perelman School of Medicine, University of Pennsylvania

Dominic Sisti is an associate professor in the Department of Medical Ethics & Health Policy at the University of Pennsylvania. He directs the Scattergood Program for Applied Ethics in Behavioral Health Care and holds secondary appointments in the Department of Psychiatry and the Department of Philosophy. Sisti's research includes the examination of ethical and policy challenges in mental health care, medical ethics in correctional health care, and ethical issues in psychedelic research and treatment. Dr. Sisti was recently elected a fellow of the Hastings Center.



Andrew Peterson, Ph.D.

Assistant Professor, Department of Philosophy, Institute for Philosophy and Public Policy, George Mason University

Andrew Peterson is an assistant professor in the Department of Philosophy and Institute for Philosophy and Public Policy at George Mason University. He is also an affiliate researcher at the University of Pennsylvania Memory Center. Previously, he was a Greenwall Faculty Scholar, and a Vanier Canada Graduate Scholar. His research centers on bioethics and the philosophy of neuroscience, with specialization in ethical issues related to neurology and human consciousness. He is a recipient of the 2021 Rising Star Outstanding Faculty Award from the State Council of Higher Education for Virginia.

Session II



Benjamin C. Silverman, M.D. (Moderator)

Senior IRB Chair, Mass General Brigham, Director of Ethics, McLean Institute for Technology in Psychiatry, McLean Hospital, Instructor in Psychiatry and Faculty Member in the Center for Bioethics, Harvard Medical School

Benjamin Silverman is the Senior IRB Chair at Mass General Brigham. He is additionally the Chair of the Mass General Brigham Embryonic Stem Cell Research Oversight (ESCRO) Committee, Director of Ethics for the Institute for Technology in Psychiatry at McLean Hospital, and at Harvard Medical School, serves as an Instructor in Psychiatry and Faculty Member in the Center for Bioethics. Dr. Silverman's academic interests center on research ethics, in particular pertaining to research conducted with vulnerable populations. His recent work has focused on the use of supported decision-making to promote inclusion and equal access in clinical research. Dr. Silverman received his medical degree from the Johns Hopkins University School of Medicine, completed his psychiatry residency at the MGH McLean Adult Psychiatry Residency Training program, and completed subspecialty fellowship training in addiction psychiatry through Mass General Brigham. He additionally completed fellowship training with the Center for Bioethics, Harvard Medical School.



Rachel Yehuda, Ph.D.

Professor of Psychiatry and Neuroscience, Director, Center for Psychedelic Psychotherapy and Trauma Research at Icahn School of Medicine at Mount Sinai; Director of Mental Health at the James J. Peters Veterans Affairs Medical Center

Rachel Yehuda is an Endowed Professor of Psychiatry and Neuroscience of Trauma. She is also Director of Mental Health at the James J. Peters Veterans Affairs Medical Center. Dr. Yehuda is a recognized leader in the field of traumatic stress studies, PTSD, and intergenerational trauma. In 2019, Dr. Yehuda was elected to the National Academy of Medicine for her seminal contributions to understanding the psychological and biological impact of traumatic stress. In 2020, Dr. Yehuda established and now directs the Center for Psychedelic Psychotherapy and Trauma Research.



Natalie Gukasyan, M.D.

Assistant Professor, Columbia University School of Medicine

Natalie Gukasyan is an assistant professor of Psychiatry at Columbia University Medical Center. After receiving her M.D. from Tulane University School of Medicine Dr. Gukasyan completed her internship and residency in psychiatry at Johns Hopkins. She went on to complete a NIDA T32 fellowship in behavioral pharmacology under the mentorship of Dr. Roland Griffiths, focusing on safety and efficacy of psilocybin-assisted therapy for people with mood and eating disorders. Before joining the faculty at Columbia, Dr. Gukasyan served as Medical Director of the Johns Hopkins Center for Psychedelic and Consciousness Research, where her research also spanned other clinical aspects of psychedelics including placebo and psychotherapy effects in treatment, as well as medication interactions.



Darron Smith, Ph.D., PA-C, DFAAPA

Associate Program Director, Research and Scholarship at MEDEX; Co-Director for the Center for Novel Therapeutics in Addiction Psychiatry

Darron Smith is an associate professor in the Department of Family Medicine at the University of Washington. He is also Co-Director at the Center for Novel Therapeutics in Addiction Psychiatry (NTAP). The center recently received a large grant from the state of Washington to study the safety and efficacy of psilocybin on first responders with PTSD and alcohol use disorder. He is a physician assistant and US Army veteran with over 25 years of healthcare experience in primary care and behavioral health. He is also MAPS-trained in MDMA-assisted therapy. Dr. Smith's research and scholarship examine US-based systems of race-based discrimination found in all societal domains, including healthcare policy and delivery. Dr. Smith's current research and practice intertwine the study of applied neuroscience, race-based trauma, and mental illness by looking at the impact of EEG biofeedback versus MDMA-assisted psychotherapy on brainwave activity in individuals with racial trauma (PTSD). Dr. Smith serves on the board of directors for the American Psychedelic Prescribers Association (APPA) and the Chacruna Institute. He also sits on the Governor's psilocybin advisory task force.



Logan Neitzke-Spruill, Ph.D.

Postdoctoral Associate, Center for Medical Ethics and Health Policy, Baylor College of Medicine

Logan Neitzke-Spruill is a post-doctoral associate in the Center for Medical Ethics and Health Policy at Baylor College of Medicine. He is a sociologist focused on exploring drug issues in the United States from psychedelic science to the overdose epidemic. His research specifically addresses the construction of scientific and medical knowledge about drugs, bioethical issues associated with drugs, how social-psychological and cultural phenomena shape drug experiences, disparities in drug overdose, as well as how the study of drugs can advance a more holistic understanding of the relationship between culture, cognition, and the brain. His dissertation, "Psychedelic Biomedicalization: Mainstreaming a 'Scientific Revolution,'" investigates the emergence of psychedelic science and examines how this movement has been shaped by processes of biomedicalization. His solo and co-authored work has appeared in *Sociological Forum*, *Journal for Studies on Alcohol and Drugs*, *Journal of Humanistic Psychology*, and *Journal of Psychedelic Studies*.

Session III



R. Cameron Wolf, Ph.D. (Moderator)

Senior Advisor, CSAP/Office of Prevention Innovation, DHHS/SAMHSA

Cameron Wolf serves as Senior Advisor at the Office for Prevention Innovation at DHHS/SAMHSA's Center for Substance Abuse Prevention focusing on the expanding use of psychedelics, including emerging therapeutic use. He has a long history working to design, implement, and evaluate programs targeted to vulnerable populations domestically and internationally. He holds a Master of Science degree from Harvard T.H. Chan School of Public Health in Health and Social Behavior, and Ph.D. from the Johns Hopkins University in Social and Behavioral Science, supported through a National Research Service Award from the NIMH/Office of AIDS Research. He was Director of Prevention at AIDS Action Baltimore before beginning public service at HRSA's HIV/AIDS Bureau in the Office of Science and Epidemiology in 2001. He supported global scale-up of PEPFAR's HIV programs at USAID from 2003, including five years based in Thailand, and was USAID's Lead Senior Advisor for Key Populations until 2022. He has published numerous articles, reports, and chapters.



Rosalind Watts, Ph.D.

Founder, ACER Integration

Rosalind Watts is a clinical psychologist, a mother, and a nature lover. Her work as the Clinical Lead for Imperial College London's psilocybin trial and subsequent role as the Clinical Director at Synthesis Institute have made her one of the most prominent voices and minds in the field of psychedelic research. Dr. Watts has been named as one of the 50 Most Influential People in Psychedelics as well as one of the top 16 Women Shaping the Future of Psychedelics. However, what sets Dr. Watts apart is her focus on integration, harm-reduction, and inclusion in the psychedelic space. Dr. Watts builds tools and structures to foster connectedness after psychedelic experiences, finding inspiration for their design from nature. The most recent of which is the integration community she's created - ACER Integration. ACER Integration aims to provide experiential education around how to integrate singular experiences into the wider collective and how to connect more deeply to the self, others, and nature.



Juliana Mercer

United States Marine Corps Veteran, Political Advocate in Promoting Safe Access for Veterans to MDMA and Psychedelics for the Treatment of PTSD

Juliana Mercer is a Marine Corps veteran who served her country honorably in and out of war zones for sixteen years. She deployed to Iraq and Afghanistan and spent five years providing holistic support to injured Marines recovering at the Wounded Warrior Battalion in San Diego. She has since channeled her passion and experience into the Veteran nonprofit arena, where she has supported Veteran transition and reintegration into civilian life. With over 20 years of experience working with and serving the veteran population, Juliana is deeply committed to supporting her brothers and sisters. In her quest to help fellow veterans and herself heal from years of personal and military trauma, Juliana found relief through an FDA-designated breakthrough therapy that fundamentally changed her life. Thus, in her current role as Director of Public Policy for the nonprofit organization Healing Breakthrough, Juliana passionately advocates for the research, training, and deployment of system-wide adoption of MDMA-Assisted Therapy in the U.S. Department of Veterans Affairs.



Laura Sanders, Ph.D.

Senior Writer, Science News magazine

Laura Sanders is a senior writer at *Science News* magazine, where she focuses on neuroscience. She earned a Ph.D. in molecular biology from the University of Southern California in Los Angeles, where she studied neuronal fates in the developing fruit fly. She holds undergraduate degrees in creative writing and biology from Vanderbilt University in Nashville. Over nearly 15 years as a reporter, she has received awards recognizing editorial excellence for her column on child development, called “Growth Curve,” and multiple stories, including a series on consciousness, a feature article on the dearth of psychiatric drugs, and an essay on brain changes caused by COVID-19.



Yuria Celidwen, Ph.D.

University of California, Berkeley, Department of Psychology and Othering & Belonging Institute

Yuria Celidwen is of Indigenous Nahua and Maya descent from the highlands of Chiapas, Mexico. Her scholarship on Indigenous contemplation examines self-transcendence and its embodiment in prosocial behavior (ethics, compassion, kindness, awe, love, and sacredness). Her broader framework is the “ethics of belonging,” encouraging awareness, intention, and relational well-being and actions toward planetary flourishing through transdisciplinary approaches involving indigeneity, cultural psychology, and contemplative sciences for epistemological equity. Dr. Celidwen works for the United Nations with a concentration on Indigenous planetary health and sustainability. A Senior Fellow at the Other & Belonging Institute of the University of California, Berkeley, she bridges communities for a sense of belonging reclaiming, revitalizing, and transmitting Indigenous wisdom and advancing the rights of Indigenous Peoples and the rights of Nature. Dr. Celidwen co-chairs the Indigenous Religious Traditions Unit of the American Academy of Religion.



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