

## 2023 OHRP Exploratory Workshop

### Draft Agenda

#### Title:

**Old Trips, New Destinations: Exploring the Ethical and Practical Considerations of Psychedelics Research**

#### Event Description:

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.

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#### Session I: Focus on Ethics and Law (20 mins per speaker + 45 mins panel)

**Moderator:** Holly Fernandez-Lynch, JD, MBe, Assistant Professor of Medical Ethics in the Department of Medical Ethics and Health Policy at the Perelman School of Medicine, University of Pennsylvania

#### **1. What makes psychedelic substances unique and what are some of the major ethical considerations for using them in research involving human participants?**

What is the psychedelic experience and how is it unique from other drugs in the treatment of mental disorders? Why is that experience seen as problematic for contemporary psychiatry and the biomedical model? Does the use of psychedelics entail novel risks or benefits that may have significant ethical implications? How might psychedelics reorient psychiatry?

**Speaker:** Duff Waring, Ph.D., J.D., Professor of Philosophy, York University

#### **2. What is the legal status of psychedelic drugs and how may potential changes at the federal or state level impact research?**

National drug policy is rapidly evolving in tandem with the growing interest in the therapeutic potential of psychedelic substances for treating a range of mental health conditions. In most jurisdictions, psychedelics remain "controlled substances." This session will explore the Controlled Substance Schedules and their impact on psychedelics research and clinical use, what it means for a psychedelic to be granted a Breakthrough Therapy Designation by the FDA, and what other mechanisms may be available to conduct psychedelics research. The session will also examine some recent state-level initiatives that may impact this research.

**Speaker: Noah Potter, J.D.**, lawyer and author

### 3. On the importance of having a solid ethical framework to evaluate psychedelics research with human participants

How can the principles of the Belmont Report be used to establish an ethical framework for psychedelics research with human subjects? What is the path forward, and what considerations beyond respect for persons, beneficence, and justice must inform an ethical framework to govern this research? What role do the principles of fairness, equity, public trust, and transparency play in this ethical framework?

**Speaker: Dominic Sisti, Ph.D.**, Director of the Scattergood Program for the Applied Ethics of Behavioral Health Care and Assistant Professor in the Department of Medical Ethics and Health Policy at the University of Pennsylvania.

### 4. What are the ethical challenges with obtaining informed consent for participation in psychedelics research?

Psychedelic substances can cause substantive and irreversible changes to one's beliefs, insights, and one's sense of self. How should researchers disclose and explain this unique aspect of the psychedelic experience to prospective research participants? Is it possible to conduct a meaningful consent process for those with no prior experience with these substances? How can we respect autonomy, including requests to withdraw consent, in participants under the influence of psychedelic substances? For those with prior experience with these substances, could the chance to access psychedelics through trial participation constitute a form of undue influence?

**Speaker: Andrew H. Peterson, Ph.D.**, Assistant Professor of Philosophy at George Mason University

## Session I Panel Discussion (45 mins)

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### Session II: Focus on the Practical Aspects of Research (20 mins per speaker + 45 mins panel)

**Moderator:** Ben Silverman, MD, Senior IRB Chair, Mass General Brigham IRB and Instructor, Psychiatry, Harvard Medical School

### 5. What are the challenges in designing scientifically sound clinical trials for examining the effects of psychedelics?

The power of psychedelics as potential treatment for mental illnesses is associated with a strong subjective psychological component. This creates problems for clinical trial designs, including the gold standard of double-blind randomized clinical trials (RCTs), for the objective examination of the biological effects of an intervention. The speaker will review these challenges and explore what meaningful options may exist for acquiring reliable generalizable knowledge about their effects.

**Speaker: Rachel Yehuda, M.D.**, Endowed Professor of Psychiatry and Neuroscience of Trauma, Mount Sinai School of Medicine

## 6. What are the challenges with evaluating and minimizing the risks of research involving psychedelics?

Since there is a strong psychological component for the effects of psychedelics, evaluating the risks of psychedelics must go beyond an understanding of their physiological effects and damages to bodily functions. This session will examine the potential for psychedelics to cause strange, unique, and even long-lasting effects on the mind, the importance of set and setting, and the impact of the guided assistance provided by therapists.

**Speaker: Natalie Gukasyan, M.D.**, Psychiatrist and Assistant Professor at John Hopkins University Center for Psychedelic and Consciousness Research.

## 7. Exploitation or inclusion? Exploring the ethical obligation and the unique challenges with including black and brown populations in psychedelic research

For the findings of research to be appropriately generalizable to benefit the populations in need, there is an ethical obligation to include black and brown populations in mental health research involving psychedelics. This session will explore the obstacles (including research funding and availability of research personnel) with conducting such research with black and brown individuals, the challenges with gaining their trust in the research enterprise, and what researchers can do to promote respect for these populations through the informed consent process.

**Speaker: Carl Hart, Ph.D.**, Mamie Phipps Clark Professor of Psychology at Columbia University

## 8. Addressing the challenges with conducting psychedelics research involving incarcerated individuals

There is a high concentration of mental illness among those currently or formerly incarcerated. PTSD and other trauma are also highly prevalent in this population. However, many are incarcerated or were formerly incarcerated because of the War on Drugs. What are the unique challenges, including social barriers like bias, stigma, and fear of prosecution, for including these populations in psychedelics research? Is there an ethical obligation to make psychedelic therapies available to these groups? How does one conduct studies involving those who are incarcerated, on parole, or formerly incarcerated and fearful of reincarceration?

**Speaker: Logan Neitzke-Spruill, Ph.D.** Candidate in Sociology at the University of Delaware

## Session II Panel Discussion (45 mins)

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## Session III: Safeguarding Public Trust; Preventing Another Psychedelics Bubble (one hour session)

**Moderator:** Ingrid Donato, B.S., Director, Office of Prevention Innovation, Substance Abuse and Mental Health Services Administration (SAMHSA)

A full hour will be devoted to a focused discussion on how to further public trust in the potential use of psychedelics to treat mental health conditions. To supplement the conversation, this session will begin with 4 distinct perspectives (8-10 mins each) prior to the open panel discussion.

1. **Rosalind Watts**, PhD, clinical psychologist and the clinical lead for the psilocybin trial at London's Imperial College. 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.
2. **Juliana Mercer**, United States Marine Corps veteran, MDMA research participant, and activist in promoting access for veterans to psychedelics for the treatment of PTSD. Invited to provide perspectives as a patient, research participant, and advocate.
3. **Laura Sanders**, PhD, journalist, senior writer at Science News, specializes in neuroscience. Asked to reflect on the role that the media play in reporting about psychedelics effects on mental illness and offer advice to scientists and policymakers on how to communicate with the public to combat hype and misinformation.
4. **Yuria Celidwen**, PhD, Senior Fellow, Other & Belonging Institute (OBI), the University of California at Berkeley, scholar of Indigenous Nahua and Maya descent from the highlands of Chiapas (Mexico). 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.

**Note: Invited guests will be asked to participate in the full-day event, not only in their segment, so that they will be able to bring their expertise to the 3 panel discussions throughout the day.**