

Creating an Ethical Framework for Psychedelic Therapy Research

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WITH MDMA-ASSISTED PSYCHOTHERAPY RECEIVING Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA), the MAPS Public Benefit Corporation (MPBC) is on the cusp of a major advance in how trauma-based disorders are treated in the U.S. and abroad. The potential to relieve human suffering on a grand scale is real, and so too are the ethical challenges. In fact, the study of psychedelic drugs has always been ethically fraught. Fortunately, the Multidisciplinary Association for Psychedelic Studies (MAPS) is sensitive to this fact, and has committed to developing an ethics program that will offer a space for ethical reflection, respectful debate, and informed decision-making regarding psychedelic research and therapy.

I am a professional medical ethicist. For the past two years, I've been in conversation with the leadership and staff of MAPS and MPBC about the ethical challenges that are woven into the fabric of psychedelic research. Many of these challenges are commonly discussed in other biomedical research settings, and they include protecting the safety of vulnerable persons and ensuring participants are competent to provide truly informed consent.

However, psychedelic research still has several unique ethical challenges.

For example, it may be difficult to fully inform participants about the potentially profound changes that may accompany a psychedelic experience. In most other drug studies, the radical transformation of one's identity is generally not an issue—but with MDMA and other psychedelics, researchers and therapists must remain sensitive to and aware of the transformation of awareness experienced by participants in order to guide them on their therapeutic journey. This requires a sophisticated kind of ethical wisdom and virtue that is beyond simple rule-following or maintaining compliance with federal regulations.

When my colleague, bioethicist Jonathan Moreno, Ph.D., and I were asked to begin developing an ethical framework for MPBC, we started by thinking through how the goals and practices of MPBC already reflected the ethical values of human subjects research that have been articulated by bioethicists over the past half century. We turned to a canonical bioethics document, the Belmont Report, which was first published in 1979 and enumerates three principles of ethical research: Respect for Persons, Beneficence, and Justice. Each of these principles has concrete applications and serve as the foundation for modern research ethics regulations. From there, we developed a set of principles that integrates values from the open science movement and lessons related to reporting conflicts of interest (Table 1).

For example, the principle of Radical Transparency reflects MPBC's commitment to publishing all of its findings—both positive and negative—in the scientific literature and on the organization's website. Radical Transparency also commits MPBC to disclosing all of the financial relationships and support it receives.

MPBC also is committed to advancing the science of psychedelics through strategic partnerships with other research organizations. This potentially includes working cooperatively with for-profit firms, whether or not MAPS receives a direct benefit from that cooperation. Again, this principle reflects the fundamental aim of MAPS and MPBC: to bring these medicines to market for the sake of patients. There may be instances where a for-profit partner makes decisions that actually inhibit access to medicines; in such cases, an MPBC ethics committee will convene to discuss the matter and determine an appropriate course of action.

Similarly, MPBC will engage the community through educational programming and public discussions of its research. The principle of Democratic Deliberation conveys the importance of community engagement in psychedelic research, which remains a socially sensitive subject.

Finally, the MPBC ethics program will be evaluated annually. We are working on developing a new kind of scorecard to measure how well the organization is living up to its ethical commitments. This tool will be the first of its kind, and may serve as a template for other pharmaceutical benefit corporations.

It is clear that both MAPS and MPBC have a strong commitment to ethics across all of their operations. In the months and years to come, this commitment will catalyze the science of psychedelics, leading to new treatments for some of the most intractable mental health conditions. 🌀

Table 1. Overview of the draft MPBC ethical framework.

Principle	Application
Respect for Persons	Ensuring voluntariness, capacity, and informed consent, harm/benefit analysis that is justifiable for individual participant or their population.
Radical Transparency	Publishing research protocols, drug sourcing information, outcomes, ancillary data, and finances.
Collaboration & Open Science	Working in partnership with other research organizations, whether nonprofit or for profit, to advance the science of psychedelics.
Justice & Fairness	Committing to fair distribution of research benefits and burdens; commitment to diversity in recruitment of participants; benefit sharing and compassionate use.
Democratic Deliberation	Maintaining open dialogue with communities involved in research; regular educational programming for participants, advocates, and the broader community.

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