

## The Hopkins-Oxford Psychedelics Ethics (HOPE) Working Group Consensus Statement

Edward Jacobs<sup>1</sup>, Brian D. Earp<sup>1</sup>, Paul S. Appelbaum<sup>2</sup>, Lori Bruce<sup>3</sup>, Ksenia Cassidy<sup>4</sup>, Yuria Celidwen<sup>5</sup>, Katherine Cheung<sup>6</sup>, Sean K. Clancy<sup>7</sup>, Neşe Devenot<sup>8</sup>, Jules Evans<sup>9</sup>, Holly Fernandez Lynch<sup>10</sup>, Phoebe Friesen<sup>11</sup>, Albert Garcia Romeu<sup>8</sup>, Neil Gehani<sup>12</sup>, Molly Maloof<sup>13</sup>, Olivia Marcus<sup>6</sup>, Ole Martin Moen<sup>14</sup>, Mayli Mertens<sup>15</sup>, Sandeep M. Nayak<sup>8</sup>, Tehseen Noorani<sup>16</sup>, Kyle Patch<sup>17</sup>, Sebastian Porsdam-Mann<sup>18</sup>, Gokul Raj<sup>19</sup>, Khaleel Rajwani<sup>11</sup>, Keisha Ray<sup>20</sup>, William Smith<sup>10</sup>, Daniel Villiger<sup>21</sup>, Neil Levy<sup>1</sup>, Roger Crisp<sup>1</sup>, Julian Savulescu<sup>22</sup>, Ilina Singh<sup>1</sup>, David B. Yaden<sup>8</sup>

1. University of Oxford
2. Columbia University
3. Yale University
4. The New School for Social Research
5. University of California, Berkeley
6. New York University
7. Emerge Law Group
8. Johns Hopkins University
9. Queen Mary University of London
10. University of Pennsylvania
11. McGill University
12. Mindlumen
13. Adamo Biosciences
14. Oslo Metropolitan University
15. University of Antwerp
16. University of Auckland,
17. The National Institutes of Health
18. University of Copenhagen
19. National Institute of Mental Health and Neurosciences, Bengaluru
20. University of Texas Health Science Center at Houston
21. University of Zurich
22. National University of Singapore

The first Hopkins-Oxford Psychedelic Ethics (HOPE) workshop convened to discuss ethical matters relating to psychedelics in August of 2023 at the University of Oxford. The organizers (BDE, DBY, EJ) aimed for a diversity of participant backgrounds and perspectives. The keynotes were given by an Indigenous scholar and a psychiatrist; other attendees included lawyers and ethicists, psychedelic scientists, anthropologists, philosophers, entrepreneurs and harm reduction actors.

The workshop was organized out of a recognition that the field of psychedelics is at a pivotal point in its history: research, clinical applications, and policy initiatives are

quickly scaling up. The use of psychedelics is expanding, and the development of new systems governing their use is already underway. These changes are happening while substantial uncertainty remains, both about the effects of psychedelics and about the ethical dimensions surrounding their use. We recognize that there is a significant risk of harms as well as potential benefits. Participants at the workshop discussed the ethical aspects of psychedelics, including research methods, clinical practices, history, law and society, spirituality, community, culture and politics that arise in relation to psychedelics.

Despite the value of these discussions, the group remains mindful that relatively few voices could be included compared to the scope of those thinking about psychedelics, and those who will be impacted by psychedelics in the coming years. Participants resolved that improving outcomes will require us to make special efforts to further increase the diversity of participant perspectives and backgrounds at future events, including patients and users (not only those who have been benefited by psychedelics, but also those who have been harmed), biopharmaceutical companies, Indigenous communities with established histories of psychedelic use, and law and policy makers.

Workshop participants discussed a draft of the current document. This document is intended to summarize our shared understanding of some of the central ethical considerations relating to psychedelics and a few recommendations to the field. Of course, on some points, there *is* no consensus yet, and there may never be. Further, there are matters on which the group was agnostic, matters which split the room, and matters which we agreed required more evidence and more discussion between the full breadth of stakeholders. Nonetheless, the signatories endorse the sentiments below and believe they are worth conveying to the field at large. More broadly, we hope that this statement is a useful contribution: to those who work with, research, or use psychedelics, as well as anyone interested in the field.

The push towards developing psychedelic drugs into licensed medicines over recent years has led to a growing recognition of the importance of carefully laying out best research, clinical, and policy practice for regulating their clinical use. Specifically, best practices should be developed and implemented to minimize risks to patients and promote benefits. There are social justice issues to address as well, such as promoting equitable access and providing appropriate benefit-sharing with certain Indigenous communities with long histories of practice with psychedelic plants.

Currently, clinical applications may dominate discourse about engagement with psychedelics. However, the roles that psychedelics have played in society have always transcended the biomedical domain -- and likely will continue to do so. Recent legislative shifts have removed criminal penalties for personal use of psychedelics in some jurisdictions, while others have moved to permit and license 'supported adult use' outside of a medical context. Alongside these shifts, interest is increasing in less-formalized uses of psychedelics in spiritual, self-developmental, wellbeing-enhancement and other contexts. Such uses remain prohibited in many jurisdictions, and while nothing in this statement

should be taken as an endorsement of illegal behavior, such practices remain deserving of serious attention and consideration.

We welcome recent analysis of psychedelics within clinical ethics, as well as from legal and regulatory standpoints, but we also acknowledge the need to consider the broader ethical implications of psychedelic use at multiple levels of analysis. Historical ethical transgressions around psychedelics - including MK Ultra, abuses of psychiatric patients and prisoners, sexual abuse and boundary violations by guides, and appropriative practices towards Indigenous communities - must neither be forgotten nor repeated.

The ethics of psychedelics is complex: psychedelic experiences can have profound - sometimes transformative - psychosocial or spiritual impacts on some users and these experiences are influenced by social and cultural factors. A comprehensive assessment of risks and benefits requires seeing things not only at the level of the individual user, but also at the socio-historical, political, public health and cultural levels. Even though we know much more about psychedelic compounds than we did 15 years ago, there is still much for us to learn and continued research is absolutely essential.

In line with our intention to convey some central issues in psychedelic ethics and a few recommendations to the field, we present the below as a 'ground floor' consensus. In each numbered section below, we present:

- (i) our shared understanding of some of the major ethical considerations relating to psychedelics (while also acknowledging points of disagreement),
- (ii) our position relating to those features,
- (iii) and our suggestions to the field.

#### I. Recognition of the special position of communities with historical use of psychedelics

- We recognize that our current understanding and practices involving psychedelics have been informed by long-accumulated knowledge of specific Indigenous communities, who have been systematically marginalized.
- Although disagreements remain about the extent to which modern medical practice with psychedelics represent a co-optation or adaptation of Indigenous practices, certain specific Indigenous groups' long experiential history with psychedelics has afforded them valuable perspectives about safeguards in practice, as well as broader considerations of engaging with psychedelics that research and practice communities might overlook.
- Indigenous groups with certain histories of psychedelic use may be subject to particular risks associated with increased decriminalization and medicalization. The Declaration on the Rights of Indigenous Peoples includes discussion of such risks, such as the unacknowledged appropriation of tangible and intangible elements of cultural tradition, as well as extractive and unsustainable practices that threaten ecosystem management and traditional ways of life.
- As such, research and practice communities have a responsibility to acknowledge or engage with Indigenous communities in a spirit of restitution, respect, and reciprocity, including the representation of Indigenous knowledge and interests in

decision-making, and an appropriate share of any financial benefit arising from the commercialization of psychedelics, or of practices or technologies that owe their origin to Indigenous knowledge..

## II. Precautionary approach to advancing scientific understanding

- While classic psychedelics are significantly safer than thought in decades past, their risks are not yet completely understood. Long-term and ‘non-standard’ potential harms (e.g., those related to changes in beliefs and outlook, as well as relational harms) in particular are understudied.
- Researchers, journal editors and IRBs have a duty to ensure that studies are conducted in a way that promotes the systematic collection of both potential benefits and adverse effects.
- The bulk of current safety data relating to psychedelics is drawn from highly unrepresentative samples: homogenous, ‘Western, Educated, Industrial, Rich and Democratic’ (WEIRD) participants taking psychedelics in tightly controlled trial contexts. Outcomes in these samples may not generalize to other contexts, including real world clinical and ‘supported adult use’ settings, as well as other group and individual use contexts.
- Real world evidence is needed about harms, harm reduction, and potential benefits outside of the trial context (e.g., recreational and retreat contexts), including quality epidemiology, implementation science, and comparative effectiveness studies.
- The valuable aim to research outcomes following psychedelic use should not transgress into privacy-violating overreach, particularly in contexts where psychedelic use is not fully legally protected.
- Many of us are open to the cautious expansion of trials, and potentially clinical practice, into populations with additional vulnerabilities who may stand to benefit from psychedelics. Here it is essential to invest further attention and effort to involve multidisciplinary voices and stakeholders with lived experience to ensure proportionate protections. Some of us hold that we must not ‘protect’ vulnerable populations by excluding them from research so that the studies do not generalize to them; others emphasize the need for better evidence from existing lines of research to enable a stronger understanding of basic mechanisms and risks before expanding research to vulnerable populations.
- Our judgments of the benefits and risks of psychedelics should not be grounded in ‘psychedelic exceptionalism’; we must avoid being more lenient, or more strict, in our assessments simply because they are *psychedelics*. However, we recognize that in many instances, psychedelics offer an opportunity to reflect on the wider systemic practices and norms that we are used to. For example, some scholars have raised concerns about the quality of medical and scientific research in general (alleging insufficient openness and transparency, undisclosed conflicts of interest, too much flexibility in statistical analysis and outcome reporting, and so on). As a relatively young field, we believe psychedelic science has an opportunity to set higher standards for research in general, and we urge actors in this space to seize this opportunity.

### III. Recognition of the legitimacy of diverse motivations to engage with psychedelics

- Despite the controlled status of psychedelic drugs in law, people can have legitimate reasons for wanting to use psychedelics that are not exhausted by their clinical applications, including spiritual, well-being, self-development, and recreational purposes.
- Different contexts of psychedelic use will come with different profiles of risk and different ethical considerations (e.g., clinical use in under-18s, and use for personal or professional development). We should not only seek to understand how to optimize risk/benefit ratios, but also attend carefully to the novel challenges that come with novel contexts.
- Non-clinical uses of psychedelics are and will likely remain the vast majority of psychedelic use. While we reject the stigmatization of drug users, we acknowledge that some practices and patterns of use are harmful. Developing a better understanding of how to reduce harms in these contexts should be a priority.
- This statement, but not all its contributing members, remains agnostic about how best to regulate different models of use, recognising the challenges of avoiding overregulation and underregulation while seeking to balance safety and access.
- While decisions about best regulatory practice will depend on both ethical and empirical considerations, a half-century of drug prohibition is sufficient to demonstrate that best practice will not involve criminal convictions for personal use or possession of psychedelics. Criminalizing the use of drugs, or the possession of test-kits aimed to reduce harms, was strongly opposed as unethical by the majority of the workshop members. We acknowledge a long history of drug laws that have disproportionately negatively impacted minoritized communities, especially, within the U.S. context, Black, Latino, and Indigenous men and their families

### IV. Need for education

- A wide range of groups (including the public, medical associations, law enforcement, institutional review boards, insurers and the media) can benefit from being well-informed about psychedelics. The psychedelic research community has a responsibility to strive towards providing impartial information about psychedelics, free of bias or hype (either overly positive or negative), including their cultural dimensions, their characteristic effects, their potential harms, benefits, and uncertainties surrounding their mechanisms of action and effects.
- While rigorous scientific data is indispensable in pursuit of beneficial outcomes, the scientific psychedelic research community is not the sole source of knowledge. Advancing understanding requires learning from a breadth of groups, such as Indigenous communities with histories of psychedelic practice, underground practitioners, recreational users, and others, including those who have been harmed in various ways by psychedelics.
- Psychedelic researchers should seek to provide or make accessible harm-reduction information: they have particular expertise relating to risks, and people may be drawn to the use of psychedelics in uncontrolled contexts because of recent research.

Providing harm-reduction information is a valuable service, and does not equate to the endorsement of potentially risky or illegal practices.

- Psychedelics are sufficiently distinct that regulatory gatekeepers unfamiliar with them may unwittingly over-regulate or under-regulate them. The scientific and scholarly research communities should undertake efforts to support gatekeepers in their decision-making by providing information about the relevant empirical and ethical dimensions of psychedelics.

## V. Consent

- The unpredictable nature of psychedelic experiences presents particular challenges for securing adequate consent.
- We encourage the development of a wide range of resources seeking to inform prospective users about psychedelic experiences and their potential risks and benefits, including scientific data, testimony from similar users, and educational materials. Determining best practice here will depend on collaboration between researchers, practitioners, and those with lived experience.
- Psychedelics can be sexually activating for some users, and users should be mindful of this across contexts, including clinical, recreational, spiritual, and other settings. Sexual touch is never appropriate in therapeutic settings, and practitioners and users must be aware that 'sexual touch' is not easy to clearly define: psychedelics can alter perceptions of touch and related social cues, and what might be innocuous in sober settings may not be during a psychedelic experience.
- The group was divided about the value and appropriateness of 'therapeutic touch' during a psychedelic experience when non-touch methods of comfort exist. We affirm the importance of honoring any refusal of therapeutic touch. While appropriately consented reassuring touch to the hand or shoulder in distress can be appropriate in some instances, we endorse the need for systematic research into further use during clinical practice, and recognize the importance of a precautionary mindset relating to therapeutic touch (e.g., the use of a 'two-stage' consent process, seeking consent for touch both before and during acute drug effects).

## VI. Equity

- An equity-oriented approach to psychedelic services is required to ensure fair outcomes, and will serve to avoid the perpetuation of inequalities that have long impaired healthcare provision for racialized and other marginalized communities.
- Relationships between biomedicine and marginalized communities have been strained by a long history of ethical transgressions, and efforts towards developing an equity-oriented approach must be mindful of special concerns relating to drugs that will impact these groups (e.g., the impact of the War on Drugs).
- We recognize that social equity programmes can have unintended adverse effects. Psychedelic initiatives aiming to develop an equity-oriented approach to policy and practice must ensure that programmes focusing on marginalized groups are collaboratively *embedded* within communities, rather than *imposed* on them, and

based on evidence (i.e., neither effectiveness nor lack of negative externalities should be assumed in the absence of research).

- Particular efforts should be made—and resources set aside—to ensure that marginalized groups are properly represented in psychedelic research and care, within research participant cohorts, therapy training programs, and policy making bodies.
- Psychedelic researchers and practitioners must be alive to the fact that people from different cultures can have different needs, preferences, and worldviews when it comes to mental healthcare. The development of psychedelic interventions needs to be culturally competent.

## VII. Professional Conduct

- Licensing structures for psychedelic practitioners must develop and articulate clear and transparent codes of conduct for working with psychedelics, including accountability structures to receive, report, and penalize transgressors. Psychedelic practitioners licensed in healthcare professions remain bound by their existing codes of conduct.
- Above these minimum requirements for ethical conduct, communities of psychedelic practitioners should establish publicly available codes detailing best ethical practice within their field.
- Ethical practice amongst psychedelic practitioners depends not only on formal rules, but also on the development of professional *cultures* that actively engage with ethical challenges encountered in practice. Practitioners and researchers are encouraged to engage in open discussion of such issues in academic publications and conferences, alongside the exploration of such aspects within supervisory or peer-group relationships.

## VIII. Special vulnerabilities around psychedelic use and risks of abuse

- The characteristic effects of psychedelics, including profound experiences, as well as increased suggestibility and decreased autonomy, can greatly increase the vulnerability of users. It is essential that proportionate safeguards are in place to minimize risks of abuse of that vulnerability (e.g., the recording, with consent, of drug sessions, with retention and review of video).
- Users of psychedelics in spiritual and therapeutic frames have sought out practitioners for compassionate pastoral and psychological support, and the exploitation of these frames represents a grave abuse of trust.
- The combination of increased suggestibility, feelings of connectedness and trust, as well as the noetic quality that psychedelics can engender, increases the potential for other forms of abuse and manipulation, including financial abuse and the imposition of practitioner beliefs or worldview. Clear and transparent codes of conduct relating to these and other forms of abuse should be core content in practitioner credentialing processes, and in ongoing professional discussions.

## IX. Importance of breadth of research to advancing understanding

- Understanding and optimizing the potential impacts of psychedelics on society will require not only rigorous scientific research, but also engagement with perspectives from many fields of study, and stakeholders from diverse backgrounds.
- We recognize the value of diverse worldviews in the study of psychedelics, including other systems of ontology and epistemology which may be challenging to reconcile. Advancing understanding will require engagement with critical and heterodox voices, and we are mindful that crucial insights will often come from stakeholders who do not have the highest cultural and economic capital.
- Psychedelic research can occur within disciplinary silos, and efforts to foster interdisciplinary exchanges should be encouraged.

#### X. Responsibility and ethics in communication

- We recognize that the often profound effects of psychedelic experiences, and the frequently highly charged attitudes about psychedelics (both positive and negative), strengthen the need for the output of evidence-based and non-hyperbolizing communications about psychedelics.
- As in any field, we recognize the existence of conflicts of interest that can distort both research agendas and reporting, underlining the need for full and transparent disclosures of all conflicts in published academic work and other communication.
- Clinics and retreat centers should disclose and make clear the cultural context, underlying beliefs or philosophy, and ‘setting’ that their practice takes place in, acknowledging that this may shape a user’s psychedelic experience.
- Researchers and the media are together responsible for the output of accurate, transparent, and non-hyperbolizing communications that raise awareness both of potential benefits and ethical considerations relating to psychedelic use, including the reality that many uncertainties remain. We encourage the development of media guidelines to support reporters seeking to write accurately about psychedelics.
- There is a wealth of insight and understanding around psychedelics held in communities outside of research institutions. Researchers must acknowledge and actively credit the sources of information they use, even where these come from outside of the peer-reviewed literature.
- Researchers should seek to make the outputs of their research as accessible as possible (e.g., publishing open access when feasible; producing lay summaries).

#### **Box. The scope of ‘psychedelics’**

We have in mind for this statement so-called ‘classic’ or paradigmatic psychedelics, defined as substances that are partial agonists of 5-HT<sub>2A</sub> receptors that produce substantially altered states of consciousness involving changes to affect, cognition, and perception. Notable

examples include psilocybin, LSD, mescaline, and DMT. Some of these (e.g., psilocybin mushrooms, peyote mescaline) are found in nature, and have been used in select Indigenous communities for ceremonial and communal purposes, within the context of particular belief systems and traditions of use. Others (e.g., LSD, synthetic psilocybin) were developed by scientists within the past century and may have different associations within Western culture.

The term 'psychedelic' was coined by psychiatrist Humphrey Osmond in correspondence with author Aldous Huxley. Roughly, the term means "mind-manifesting". In contemporary usage, 'psychedelic' has the character of a cluster concept, with paradigmatic examples at the center, and less paradigmatic examples toward the margins, with corresponding disagreement about whether the latter examples should be counted as 'psychedelics' at all.

Among these more contested examples are MDMA, ketamine, salvia, scopolamine, ibogaine, and cannabis. These substances, and various associated patterns of usage, have some things in common with the 'classic' psychedelics on which we are focusing in this article: they involve intensely altered states of consciousness lasting a few minutes to many hours, with the possibility of persisting effects lasting days, weeks, months, or even years.

However, these substances differ along a number of dimensions, such as their pharmacological mechanisms of actions, histories of use, and acute subjective effects. Thus, although some of the ethical points we raise likely will apply to these latter types of substances, we are not committing ourselves to any particular implications in those cases and instead see our statement as being primarily concerned with the paradigmatic examples of psychedelics (i.e., classic psychedelics such as psilocybin).

#### Signatories:

Edward Jacobs, Brian D. Earp, Paul S. Appelbaum, Lori Bruce, Ksenia Cassidy, Yuria Celidwen, Katherine Cheung, Sean K. Clancy, Neşe Devenot, Jules Evans, Holly Fernandez Lynch, Phoebe Friesen, Albert Garcia Romeu, Neil Gehani, Molly Maloof, Olivia Marcus, Ole Martin Moen, Mayli Mertens, Sandeep M. Nayak, Tehseen Noorani, Kyle Patch, Sebastian Porsdam-Mann, Gokul Raj, Khaleel Rajwani, Keisha Ray, William Smith, Daniel Villiger, Neil Levy, Roger Crisp, Julian Savulescu, Ilina Singh, David B. Yaden

#### Recommended Readings

Appelbaum, P. S. (2022). Psychedelic research and the real world. *Nature*, 609(7929), S95-S95.

Breeksema, J. J., Kuin, B. W., Kamphuis, J., van den Brink, W., Vermetten, E., & Schoevers, R. A. (2022). Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review. *Journal of Psychopharmacology*, 36(10), 1100-1117.

Celidwen, Y., Redvers, N., Githaiga, C., Calambás, J., Añaños, K., Chindoy, M. E., ... & Sacbajá, A. (2023). Ethical principles of traditional indigenous medicine to guide western psychedelic research and practice. *The Lancet Regional Health–Americas*, 18.

Cheung, K., Patch, K., Earp, B. D., & Yaden, D. B. (2023). Psychedelics, meaningfulness, and the "proper scope" of medicine: continuing the conversation. *Cambridge Quarterly of Healthcare Ethics*, 1-7.

- Devenot, N., Tumilty, E., Buisson, M., McNamee, S., Nickles, D., & Ross, L. K. (2022). A Precautionary Approach to Touch in Psychedelic-Assisted Therapy. *Bill of Health*.
- Earp and Savulescu (2021). *Love Drugs: The Chemical Future of Relationships*. Stanford, CA: Redwood Press.
- Evans, J., Robinson, O. C., Argyri, E. K., Suseelan, S., Murphy-Beiner, A., McAlpine, R., ... & Prideaux, E. (2023). Extended difficulties following the use of psychedelic drugs: A mixed methods study. *PLOS ONE*, *18*(10), e0293349.
- Fogg, C., Michaels, T. I., de la Salle, S., Jahn, Z. W., & Williams, M. T. (2021). Ethnoracial health disparities and the ethnopsychopharmacology of psychedelic-assisted psychotherapies. *Experimental and Clinical Psychopharmacology*, *29*(5), 539.
- Jacobs, E., Murphy-Beiner, A., Rouiller, I., Nutt, D., & Spriggs, M. J. (2024). When the Trial Ends: The Case for Post-Trial Provisions in Clinical Psychedelic Research. *Neuroethics*, *17*(1), 3.
- Jacobs, E., Yaden, D. B., & Earp, B. D. (2023). Toward a Broader Psychedelic Bioethics. *AJOB neuroscience*, *14*(2), 126-129.
- McGuire et al. (*under review*). Developing an Ethics and Policy Framework for Psychedelic Clinical Care
- McGuire, A. L., Lynch, H. F., Grossman, L. A., & Cohen, I. G. (2023). Pressing regulatory challenges for psychedelic medicine. *Science*, *380*(6643), 347-350.
- McMillan, R. M. (2022). Psychedelic injustice: should bioethics tune in to the voices of psychedelic-using communities?. *Medical Humanities*, *48*(3), 269-272.
- Neitzke-Spruill, L. (2020). Race as a component of set and setting: How experiences of race can influence psychedelic experiences. *Journal of Psychedelic Studies*, *4*(1), 51-60.
- Noorani, T. (2021). Containment matters: Set and setting in contemporary psychedelic psychiatry. *Philosophy, Psychiatry, & Psychology*, *28*(3), 201-216.
- Ortiz, C. E., Dourron, H. M., Sweat, N. W., Garcia-Romeu, A., MacCarthy, S., Anderson, B. T., & Hendricks, P. S. (2022). Special considerations for evaluating psilocybin-facilitated psychotherapy in vulnerable populations. *Neuropharmacology*, *214*, 109127.;
- Thrul, J., & Garcia-Romeu, A. (2021). Whitewashing psychedelics: racial equity in the emerging field of psychedelic-assisted mental health research and treatment. *Drugs: Education, Prevention and Policy*, *28*(3), 211-214.
- Yaden, D. B., Potash, J. B., & Griffiths, R. R. (2022). Preparing for the bursting of the psychedelic hype bubble. *JAMA psychiatry*, *79*(10), 943-944.
- Yaden, D. B., Earp, B. D., & Griffiths, R. R. (2022). Ethical issues regarding nonsubjective psychedelics as standard of care. *Cambridge Quarterly of Healthcare Ethics*, *31*(4), 464-471.