



HOPE

THE HUB AT OXFORD FOR
PSYCHEDELIC ETHICS



JOHNS HOPKINS

Center for Psychedelic &
Consciousness Research

Response to the Request for Information on Training and Care Delivery Models for Safe Administration of Potential FDA-Approved Psychedelic Therapies in Ambulatory Clinical Settings, as submitted by the Hub at Oxford for Psychedelic Ethics

August 14, 2026

Introduction

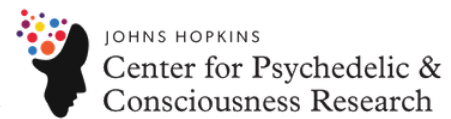
About the Submitting Organization

The Hub At Oxford for Psychedelic Ethics

The Hub at Oxford for Psychedelic Ethics (HOPE) is an interdisciplinary center that aims to develop sustainable frameworks for psychedelic ethics, law, and policy. It serves as an international academic and policy hub to bring together researchers and other stakeholders to advance psychedelic ethics, law and policy.



The Center for Psychedelic and Consciousness Research (CPCR) at Johns Hopkins University School of Medicine is the largest, most productive, and most comprehensive psychedelic research center in the world. It is the research center that is most responsible for sparking the now-global research renaissance on the therapeutic potential of psychedelics. With a mission to advance the scientific understanding of psychedelics, including risks and benefits, the center conducts rigorous scientific trials. Researchers aim to elucidate the mechanisms driving psychedelic effects and their therapeutic efficacy, while also providing evidence-based education to clinicians and the broader community. Website: hopkinspsychedelic.org



About the Authors of this Response

Authors: Edward Jacobs,¹ Katherine Cheung,^{1,2} David B. Yaden¹

¹*Center for Psychedelic and Consciousness Research, Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine*

²*Bloomberg School of Public Health & Berman Institute of Bioethics, Johns Hopkins University*

The safety and benefit estimates that currently support psychedelic treatments in psychiatry are drawn almost entirely from clinical trials, and, though to a much lesser extent, from data on state supervised use models. Estimates from both of these contexts cannot be transferred without qualification to a Federally Qualified Health Center context. The level of care in many clinical practices diverges from the contexts that have generated risk data, particularly clinical trials, which have typically included a great deal of safeguards that will be unavailable in clinical practice. Relying uncritically on data generated from clinical trials is liable to lead to underestimated risk in clinical contexts due to fewer safeguards and less oversight. While state models can provide some relevant data, Oregon's model, for example, has in large part been used for wellness or self-exploration rather than for serious mental illness. Safe implementation in FQHCs will therefore require evidence, training standards, and care-delivery models specifically designed for the populations, staffing constraints, and clinical realities of these settings.

Our response builds on the implications of this uncertainty about generalizing the risks and benefits from the available evidence to the FQHC context. Working from the safety practices in clinical trials, we propose some minimum safety requirements for ambulatory settings, while also identifying where resource-limited clinics can most defensibly retain flexibility. These requirements are informed by standards of care elsewhere in medicine. These are deliberately conservative starting requirements, with flexibility added and the minimum standards revised as real-world outcome data accumulate..

Our response focuses on a subset of the questions posed by the RFI: 1) workforce, 2) requirements for safe administration in an ambulatory clinic, and 3) technology questions when they bear on the first two sets of questions. We do not address facility, storage, security, or inventory requirements. These questions, alongside those of clinical workflow redesign, and the ideal environment for psychedelic administration, are better answered by clinicians and health center operators. As scientists and bioethicists working in the clinical medical research context, we focus on the areas that most fit within our expertise and experience.

Working from limited data

The evidence for safely and effectively delivering psychedelic treatments in routine clinical care has two important gaps. The first is **safeguards**: clinical trial safety data come from highly controlled settings with strict screening, structured preparation and integration, typically two trained facilitators during dosing sessions, and medical backup. The more real-world care differs from these conditions, the less certain we can be that trial safety estimates will apply. The second is **population**: while AE data from Oregon's psilocybin services program (a state-level supported adult use model) may be cited as reassuring, that data comes from a self-selected population that frequently reports using psilocybin services for no clinical indication, in a context with comparatively limited reporting requirements. Meanwhile, the population named in April's Executive Order, people with serious mental illness, is among the groups most frequently excluded from clinical trials.

In the absence of dismantling studies to isolate which of the many precautions used by trials carry their safety signal, we cannot yet conclusively say on the strength of data alone which safety features might be relaxed for routine care. As such, in the absence of direct evidence, the safety floor we propose is disciplined by three principles.

Reasoning from analogous cases in medicine. Where features of psychedelic treatments are shared by or analogous to established interventions, the standards of care that already govern those interventions should inform practice. Any drug that induces an hours-long perceptual/cognitive incapacitation is not suitable as a take-home pharmacotherapy. In other areas of medicine that involve such incapacity (such as procedural sedation and electroconvulsive therapy recovery), continuous trained observation, with discharge governed by defined recovery criteria, is the norm.

Direction of error. Serious adverse event (SAE) rates in modern psychedelic trials are encouraging, but highly population-conditional. A recent meta-analysis from our group found no SAEs reported among healthy participants, but a rate of some 4% among those with pre-existing neuropsychiatric disorders (Hinkle et al., 2024), a figure itself conditioned on trial-grade screening and the near-exclusion of serious mental illness. Careful screening has been endorsed as among the most important mitigations against inducing psychological destabilization (King et al., 2026). In the clinically more complex, less-screened population this initiative is likely to reach, trial estimates are more likely to understate risk than to exaggerate it.

Reasoning from function to requirement. Without definitive evidence of which trial features carry the safety signal, we can still ask what each feature is for. Medical emergencies require both preventative and responsive defences, requiring medical evaluation before administration sessions and close-at-hand medical availability during. Psychological destabilization requires a trained clinician to be continuously present, and misconduct requires a second person present. Requirements that discharge key functions are part of the floor for safety, whereas those with weaker ties to safety functions (e.g., the aesthetics of the setting, the therapeutic modality, the credentials attached to auxiliary roles) are where flexibility can most defensibly be sought.

Recommendations for practice

Our recommendations (Table 1) focus on functions that must be met in routine psychedelic care, rather than specifying fixed ratios or practitioner credentialing. For each requirement that we propose, we flag potential areas of flexibility that might be considered for delivery in very resource-limited clinics. Above the floor, safety is jointly produced by several levers: screening stringency, the number and experience of in-room providers, patient complexity, and intensity of follow-up. These plausibly compensate for each other in part, with flexibility in one best purchased by conservatism in the others, but they do not substitute for the floor itself: stringent screening, for example, does not buy out the need for an accountable licensed clinician.

Table 1: Proposed initial requirements for safe delivery of psilocybin-like treatments in ambulatory settings, with named flexibilities for resource-limited clinics.	
<i>The Safety Floor: Functions that should be met for safe and effective delivery of psilocybin-like treatments</i>	<i>Options for flexibility in delivery</i>
Screening/triage. An initial broad screen may be conducted by a non-medical provider; defined risk signals must trigger triage to an appropriately qualified clinician for clearance or consultation. Screening should not be conducted on the same day as administration. Final eligibility sign-off is provided by a licensed prescriber acting within their scope of practice, or on the documented advice of a physician where risk signals are medical (e.g., drug interactions, cardiovascular contraindications). These determinations, like diagnostic ambiguities (e.g., bipolar vs unipolar depression) require clinical judgment and cannot be delegated or automated. Initial eligibility criteria should hew closely to the criteria of the trials that have generated the current evidence.	• Who performs the initial screen, including trained non-licensed providers. • Screening remotely is feasible, especially where local psychiatric capacity is limited. • Specific thresholds, documented and revisable in light of new evidence. • Broadening eligibility towards populations excluded by trials is a central purpose of the scheduled review described below.
Presence. Each patient is continuously attended throughout acute drug effects by, at minimum, a trained provider, with a licensed clinician responsible in the room. Providers in training may form part of the in-room team under that clinician's supervision, but must not constitute the majority of clinical presence.	• The setting itself (including its aesthetics) should not be prescribed, so long as the space remains monitoring-capable. • Therapeutic orientation or modality used need not be prescribed, and group dosing models can alleviate some staffing pressure.
Licensure A provider holding appropriate state licensure is present and responsible for safety and practice for every drug administration session.	• Trained providers without independent licensure can undertake screening, preparation and follow-up, provided that escalation to senior clinicians is available.

Medical cover Medical evaluation before drug administration; on the day of administration attending clinicians confirm no relevant changes (e.g., new medications, acute deterioration) since screening. Medical availability within a defined response time throughout administration sessions.	• The continuously-present monitor need not hold a medical degree, because medical capability is separately guaranteed on-call. (See exemplar configuration)
Accountability At least two appropriately trained providers are present during administration, or the session is recorded, as a check on misconduct. Recording deters and evidences misconduct but cannot interrupt it, and raises consent and data-security questions that require resolution before deployment; a second staff member able to observe and intervene is the more complete safeguard.	• Which credential(s) or license the second provider holds. • In group dosing models where screening is correspondingly tightened, an overseeing licensed clinician may discharge this function at group-level.
Discharge Readiness for discharge is determined by a licensed clinician, in person, and documented against stated criteria, including confirmation of safe passage home, with an escort as default.	• Specific criteria can be set clinically and locally, rather than centrally prescribed. • Where no escort is available, alternatives that discharge the same function (e.g., extended observation, clinic-arranged transport) prevent the requirement from excluding socially isolated patients.
Follow-up. Structured follow-up through the post-administration period is likely beneficial for enduring symptom relief, but at a minimum must check for AEs, including psychological destabilization and suicidality, that can arise in the days and weeks following treatment.	• Intensity, therapeutic intent, and the mix of providers undertaking follow-up may vary. • Lower-intensity contact may be provided by trained providers under supervision, with escalation available.
Reporting Standardized reporting of outcomes and adverse events to a common registry to support review of safeguards in response to ecologically valid evidence.	• Reporting instruments and burden calibrated to health center capacity, aligning where possible with existing in-center reporting infrastructure.

Formulations. While the functions we specify above generalise across psychedelic compounds, the provisions that they require do not transfer straightforwardly. The above floor was written with classic psychedelics, and psilocybin in particular, in view. The duration and depth of acute impairment, as well as the medical risk, shape what is needed for safe delivery and therefore the content of screening and intensity of medical cover required. For most classic psychedelics these vary in degree, though some drugs have qualitatively distinct risk profiles. Ibogaine's documented cardiac risk, including fatalities outside of monitored settings, would demand cardiac-specific screening and continuous physiological monitoring that the provisions above were not constructed to guarantee.

Telehealth across the phases of care. Some phases of treatment are amenable to remote delivery. The initial screen, escalating consultations, and eligibility sign-off can be conducted via telehealth, which may be of particular value where local psychiatric capacity is limited. Screening is required in advance of, and separately from, the administration day itself, to allow consultation and medical review to proceed unhurried and with all due diligence. While the follow-up process is amenable to remote delivery, remote monitoring of administration sessions, in lieu of a clinician in the room, is not appropriate while a patient is under acute drug effects. Discharge, a judgment about a patient who may not have fully regained their faculties, should be assessed in person rather than delegated to remote assessment.

Preparation and consent. Familiarity with psychedelic treatments is concentrated in higher socioeconomic status groups, and clinics should emphasise preparation and consent, especially where they serve underserved communities. Training for those leading consenting sessions and preparation should include competence in preparing patients with no prior exposure to psychedelic concepts, addressing unwarranted expectation and unwarranted fear alike, in language and formats that match the community served.

Use of digital and AI tools within treatment. Well-validated AI tools may defensibly assist in screening triage, workforce training, and integration support, but as adjunctive technologies under human oversight instead of as replacements. Two functions especially resist full delegation: monitoring during administration sessions must carry the on-site capacity to act, not merely detect, and surveillance for later-emerging AEs including suicidality requires a clinician who owns review and escalation.

Revisions to practice guidelines. Any defined safety thresholds should be time-limited and revisited. We recommend a review at 18 months from the first delivery of an approved psychedelic in a health center setting, assigned to whichever body ultimately carries the eventual certification or coverage conditions, and informed by the reporting requirements outlined above.

An exemplar configuration

One configuration to these standards, provided as illustration rather than requirement, is as follows: a cohort of four patients is dosed simultaneously. Each patient is individually attended throughout administration by their own monitor, and the group is jointly overseen by a licensed medical provider, who carries no patient of their own but leads the room, discharges the accountability function, and provides medical availability during the session. One or two of the individual monitors may be providers in training, attending a patient under the lead's supervision.

Grouping patients in a shared session this way eases the workforce capacity problem while continuing to provide dedicated attention for each patient, as well as the necessary oversight, accountability, medical cover and licensed responsibility for the room. This configuration reflects those used in early feasibility trials of group and community-based psilocybin treatment, without SAEs attributable to psilocybin (Lewis et al., 2023; Agrawal et al., 2024). Group size, trainee proportion, and patient complexity all plausibly erode the finite safeguard of experienced attention per-patient. Flexibility in one parameter is best purchased by conservatism in the others, rather than relaxing all simultaneously.

References

- Agrawal, M., Richards, W., Beaussant, Y., Shnayder, S., Ameli, R., Roddy, K., ... & Thambi, P. (2024). Psilocybin-assisted group therapy in patients with cancer diagnosed with a major depressive disorder. *Cancer*, 130(7), 1137-1146.
- Hinkle, J. T., Graziosi, M., Nayak, S. M., & Yaden, D. B. (2024). Adverse events in studies of classic psychedelics: A systematic review and meta-analysis. *JAMA psychiatry*, 81(12), 1225-1235.
- King, F., Zambrano, J., Mauney, E., Nigam, K., Forcen, F. E., Barnett, B. S., ... & Stern, T. A. (2026). Psychological Adverse Effects of Psychedelic Use. *The primary care companion for CNS disorders*, 28(3), 25f04172.
- Lewis, B. R., Garland, E. L., Byrne, K., Durns, T., Hendrick, J., Beck, A., & Thielking, P. (2023). HOPE: a pilot study of psilocybin enhanced group psychotherapy in patients with cancer. *Journal of pain and symptom management*, 66(3), 258-269.