Engaging Your IRB: A Guide for Psychedelic Researchers

This resource is designed to help investigators pursuing psychedelic administration studies to engage productively with Institutional Review Boards to advance ethical psychedelic science.

WHAT CAN YOU HELP YOUR IRB UNDERSTAND?

A recent survey of IRB chairs found that they are largely open-minded about psychedelics and psychedelic research. They report similar confidence reviewing psychedelic and non-psychedelic protocols. However, they note several areas of concern aligned with unsettled issues in the field and may lack familiarity with psychedelic risks and benefits, appropriate safeguards for psychedelic administration, and adjustments that may be needed to secure adequate informed consent in psychedelic research. To support efficient and effective review, address the following elements in your protocol, as relevant.

THE SCIENCE – CLARIFYING THE BASICS OF PSYCHEDELIC DRUGS AND STUDY DESIGN		
☐	**Psychedelic science**	What is known, what isn't, and what is actively debated about the psychedelic drug(s) under investigation?
☐	**Effects, risks, benefits**	Address the short- and long-term risks and benefits of the psychedelic drug(s) under investigation, as well as their magnitude and likelihood. Clarify what effects are expected, which is also relevant for reporting.
☐	**Areas of potential IRB uncertainty**	IRBs may have gaps in knowledge or misconceptions about psychedelic risks, including about abuse and overdose potential, psychosis (including relevance of family history), suicidality, and neurotoxicity. Address each proactively with clear information and references, including areas of uncertainty and limited data.
☐	**Blinding in psychedelic research**	Describe the study's approach to blinding (e.g., use of an active placebo or comparator) or explain why blinding is not feasible and how the study design otherwise limits bias. (FDA guidance suggests use of blinded central raters, blinding questionnaires, complementary trial designs, etc.)
☐	**Expectation effects**	Describe how the study addresses expectation effects on the part of investigators and participants (e.g., through expectancy evaluation questionnaires, independent outcome assessment, standardized facilitator training, or other measures to limit the influence of enthusiasm, skepticism, or other prior beliefs on results).
PARTICIPANT SAFETY — PROPORTIONATE SAFEGUARDS AND RATIONALE		
☐	**Risk minimization across the study timeline**	Describe approaches to minimize risk before, during, and after psychedelic dosing sessions, including screening, contraindications (medical conditions, possible drug interactions), medical monitoring, presence of an on-call physician during administration, and post-study follow-up (duration and type). Clarify if/when discretion will be permitted to allow enrollment/continued participation following acceptable physical exam.
☐	**Set and setting**	Explain meaning (including attention to expectancy, context), why it matters, and how it is addressed.
☐	**Facilitators and monitors**	Describe the number, credentials, and clinical experience of facilitators and monitors, clearly explaining their respective roles. If fewer than 2 monitors will be present, explain why this is sufficient. (FDA guidance calls for observation by 2 monitors for the duration of the administration session: a lead monitor who is a health care provider with graduate-level training and clinical experience in psychotherapy licensed to practice independently and an assistant monitor with a nursing or bachelor's degree and at least 1 year of clinical experience in a licensed mental health care setting.)
☐	**Physical touch**	Describe the approach to touch during sessions and how participant preference will be elicited/respected.
☐	**Rescue medication, emergency protocols**	Specify what medications are available to block psychedelic effects, if needed, as well as decision thresholds/discretion for use and how emergencies will be handled.
☐	**Discharge criteria**	Define how fitness for discharge will be determined after dosing and how to approach a participant seeking withdrawal before discharge criteria are met.
☐	**Psychological support**	What psychotherapy or psychological support is provided by the study, including preparation and integration sessions and/or other types of support? What is available if participants experience distress after psychedelic administration? Explain the rationale for the study's approach to psychotherapy or psychological support, what evidence supports that rationale, and what model will be used.
☐	**Long-term monitoring**	Describe the type and length of participant monitoring following psychedelic administration. If less than 12 months, explain the rationale and why this is sufficient. (FDA guidance suggests 12 weeks of monitoring for treatment effect, followed by 12 months of long-term follow-up.)
☐	**Adverse events (AEs) and unanticipated problems (UPs)**	Define what counts as an AE and/or UP in this study for purposes of recording, reporting to FDA and the IRB, and participant intervention, with particular attention to challenging experiences. (FDA guidance defines AEs to include "any untoward medical occurrence," including euphoria, hallucinations, and cognitive alterations. The guidance further indicates AEs should be monitored and reported as a safety concern, even if hypothesized to be associated with therapeutic response.)
PARTICIPANT VULNERABILITY – PROTECTION WITHOUT PER SE EXCLUSION		
☐	**Diagnosis-based vulnerability**	Address how participants with mental health conditions or terminal diagnoses will be protected. Note that neither necessarily precludes an individual's capacity to consent to research, which must be assessed separately from diagnosis. Additional consent procedures may be appropriate (see below).

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☐	**Administration-based vulnerability**	Describe how vulnerability arising during or after administration sessions (e.g., due to destabilizing effects and heightened suggestibility) will be identified and addressed.
☐	**Other special populations**	Describe additional protections for populations with heightened vulnerability (e.g., adolescents, incarcerated individuals, individuals with cognitive impairment).
INFORMED CONSENT		
☐	**Understanding the psychedelic experience**	Describe how participants will be prepared to understand the psychedelic experience before dosing (e.g., changes in perception, cognition, judgment, and suggestibility, as well as ineffability and transformative potential). Clarify approaches to touch during psychedelic administration.
☐	**Consent issues during psychedelic administration**	Explain any constraints that will be imposed on participant decision-making while under the influence of psychedelics during dosing sessions, such as approaches to a participant's stated desire to leave the facility, withdraw from the study, or alter previous agreements regarding touch.
☐	**Therapeutic misconception, hype**	Describe how consent materials will minimize potentially inflated participant expectations of personal benefit. Remove or carefully qualify language emphasizing that a drug is "natural" or is known to be safe and/or effective based on historical use outside clinical contexts.
☐	**Consent approaches for special populations**	Address any necessary adjustments to the consent process for special populations, such as additional preparation or extended consent discussions, or explain why adjustments are not needed.
PRIVACY, CONFIDENTIALITY, AND LEGAL RISKS		
☐	**Privacy and confidentiality**	Address confidentiality protections for participants, including for self-reported illicit drug use (if applicable) and any session recordings. Consider whether a Certificate of Confidentiality (CoC) should be sought. CoCs are issued automatically for NIH-sponsored research and protect researchers from being compelled to disclose identifiable research data in legal proceedings. Non-NIH-funded studies can also apply.
☐	**Legal, employment, and social risks**	Describe protections against legal, employment, or other social risks, including stigma, that may be associated with psychedelic administration research – or explain why such risks are unlikely given study design and authorization.
☐	**Local legal status**	Describe the local legal status of study drug(s) and any impacts on the study.
☐	**Secure drug storage**	Explain the study's approach to storage of controlled substances in compliance with DEA requirements.

ENGAGING YOUR IRB

IRBs are usually generalist bodies, often without specialization in psychedelics or psychiatric research. Their role is to protect the rights and welfare of study participants. It is the researcher's responsibility to make sure the IRB has the scientific background needed for their ethical analysis. It is appropriate for the IRB to ask questions and to help researchers identify ethical concerns they may have overlooked. If the IRB suggests a change that you believe is not necessary to protect participants or that might unnecessarily impede the research, explain your reasoning and be prepared with better alternatives.

Experienced psychedelic researchers report largely positive IRB experiences, which they attribute to collaboration and education. Consider taking the following steps:

Steps for productive IRB engagement

- Meet with the IRB office to understand their familiarity with psychedelic research; as appropriate, offer to educate the IRB through meetings with staff and board members about psychedelic research in general and about your specific protocol
- Build relationships and rapport with the IRB chair and staff; help them understand your research team's experience with psychedelics
- Seek feedback on your plans and address concerns prior to formal protocol submission
- Avoid overstating the expected benefits of your research
- Provide explanations for approaches that may be perceived as increasing risks compared to alternatives
- View the IRB as a collaborator toward ethical psychedelic research

FOR MORE INFORMATION

These recommendations for IRB engagement are based on empirical findings from two studies reported here:

- Robinson, J. O., Xiong, R. (Aria), Neitzke-Spruill, L., Purcell, A., Sisti, D., McGuire, A. L., & Fernandez Lynch, H. (2026). US Institutional Review Board Perspectives Regarding Psychedelic Research. *Psychedelic Medicine*. https://doi.org/10.1177/28314425261445746
- Neitzke-Spruill, L., Robinson, J.O., Purcell, A., Sisti, D., McGuire, A. L., & Fernandez Lynch, H. Investigators' Experiences with IRB Oversight of Psychedelic Research. Accepted at *Ethics and Human Research*. Preprint available on SSRN: https://dx.doi.org/10.2139/ssrn.7088898

FDA's Guidance for Industry, Psychedelic Drugs: Considerations for Clinical Investigations, July 2026, is available here: https://www.fda.gov/media/169694/download (Note: This guidance is largely geared to how to conduct trials in a way that can support psychedelic drug approval by FDA; it may be less relevant to other contexts.)

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