

Research and Continuous Improvement COMMITTEE PURPOSE & RESPONSIBILITIES

PURPOSE



Ensure that practitioner preparation, research activities, harm-reduction practices, and program evaluation for medical psilocybin services in New Mexico are grounded in scientific evidence, ethical standards, and continuous quality-improvement principles.

RESPONSIBILITIES



- 1. Recommend guidelines for research and data collection:**
 - Core data elements (practitioners & DOH),
 - Outcome-monitoring and adverse-event reporting standards
 - Ethical research practices (tribal & culturally specific)
 - Evaluation frameworks (safety, outcomes, trends).



- 2. Recommend harm-reduction and quality improvement practices:**

- Risk-screening & medication interaction guidance
- Emergency preparedness & crisis-response
- Informed consent & patient education materials
- Mechanisms for updating standards as new evidence emerges.

Research & Best Practices

Evidence, Regulations, and Safety Protocols

Quality Improvement & Clinical Outcomes

Project ECHO (UNM) to host regular didactics, case study presentations, and build knowledge capacity throughout the Medical Psilocybin system (trainers, facilitators, growers)

<https://projectecho.unm.edu/>

Usona Institute Investigator's Brochure Comprehensive investigator's brochure detailing psilocybin safety and efficacy data.

https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/psilocybin-ib-v4_non-editable.pdf

Compass Pathways Phase 3 Trial (COMP360) Announcement of primary endpoints achieved in the first Phase 3 trial for Treatment-Resistant Depression.

<https://ir.compasspathways.com/News--Events-/news/news-details/2025/Compass-Pathways-Successfully-Achieves-Primary-Endpoint-in-First-Phase-3-Trial-Evaluating-COMP360-Psilocybin-for-Treatment-Resistant-Depression/default.aspx>

Academic Evidence for Psychedelics A non-exhaustive repository of academic evidence regarding the therapeutic use of psychedelics.

<https://docs.google.com/spreadsheets/d/1b7ECt6a3TpjJ8a9UI2tul1ZsT3xaxGbz8KMj8TdFp1o/edit?gid=1761938101#gid=1761938101>

Regulations (US & International)

Colorado Regulations Official regulations for the Colorado Natural Medicine Health Act.

<https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=11610&fileName=4%20CCR>

Colorado Advisory Board Priority Questions Priority questions identified by the Colorado Advisory Board to guide implementation.

<https://psychedelicalpha.com/wp-content/uploads/2023/08/All-Priority-Questions.pdf>

Colorado Advisory Board Recommendations Official recommendations provided by the Colorado Advisory Board for the Natural Medicine Program.

<https://drive.google.com/file/d/13NBY7BdAygG1TL5SOV68sI70Li7WmkBI/view>

Oregon Regulations Administrative rules governing the Oregon Psilocybin Services program.

https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/333-333_10.24.25_rules-with-redline.pdf

Alberta CA Psychedelic Drug Treatment Services Standards Operational standards for psychedelic drug treatment services in Alberta.

<https://open.alberta.ca/dataset/a9adf7fa-bc51-414b-9230-dde265220ee9/resource/36ab2f25-cf94-4957-b07a-a421fcad960f/download/mha-pschedeli-c-drug-treatment-services-standards.pdf>

MAPS Canada Tip Sheet Tip sheet for navigating Health Canada's medical psilocybin program.

<https://www.mapscanada.org/wp-content/uploads/2025/11/MAPS-Canada-SAP-Tipsheet-Second-Edition-Updated11-28-2025.pdf>

Code of Ethics & Equity Resources

APPA Code of Ethics Professional practice guidelines and code of ethics for psychedelic therapy.

<https://www.brainfutures.org/wp-content/uploads/2023/08/Professional-Practice-Guidelines-for-Psychedelic-Assisted-Therapy-Aug-2023.pdf>

Colorado Ethical Code Ethical code framework for Colorado practitioners.

https://drive.google.com/file/d/1mlkamsv6_SYdml3qfHgGnuE0cvQylZx0/view

Alberta CA Incident Reporting Guidelines A decision document created to assist when to submit a critical incident or duty to notify form

<https://open.alberta.ca/publications/psychedelic-drug-treatment-services-critical-incident-reporting>

Oregon Code of Ethics Ethical principles and code of conduct for Oregon facilitators.

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Ethical%20Principles-Code%20of%20Conduct%20for%20Jan%206%20Meeting%201-2-2022.pdf>

Oregon Client Bill of Rights

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Client-Bill-of-Rights.pdf>

Indigenous Communities Working Group Report Recommendations from the Federally Recognized American Tribes and Indigenous Communities Working Group.

<https://cdn1.site-media.eu/images/document/17573145/FederallyRecognizedAmericanTribesandIndigenousCommunityWorkingGroupReport-Copy-rGr0gv2AJ26jJPEd000onA.pdf>

Informed Consent & Risk Screening

Oregon Client Service Guide Information guide provided to clients entering the Oregon program.

https://docs.google.com/document/d/1w2Zt21sCyPWqmyEwLwnJtEurNimKIX5mpV09Uty_JNI/edit?tab=t.0

Oregon Client Intake Form Standardized client intake form for Oregon services.

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Client-Information-Form.pdf>

Mood Disorder Questionnaire (MDQ) Screening tool for identifying mood disorders and bipolar spectrum conditions.

<https://psychiatryonline.org/doi/10.1176/appi.ajp.157.11.1873>

Psilocybin Mushroom Interaction Checker Tool to check for potential drug interactions with psilocybin.

<https://www.psychedelicinteraction.com/>

C-SSRS Columbia-Suicide Severity Rating Scale Scale for assessing suicide risk and severity.

<https://cssrs.columbia.edu/the-columbia-scale-c-ssrs/about-the-scale/>

MDQ Mood Disorder Questionnaire This report describes the validation of a new brief self-report screening instrument for bipolar spectrum disorders.

<https://psychiatryonline.org/doi/10.1176/appi.ajp.157.11.1873>

Tools for Baselines & Follow-up

Depression Scales (MADRS) Montgomery–Åsberg depression rating scale for assessing depression severity.
<https://PMC6878407/>

Patient Health Questionnaire for depression (PHQ-9) Checklist for assessing depression-related symptoms
<https://PMC1495268/>

PTSD Checklist (PCL-5) Checklist for assessing PTSD symptoms according to DSM-5 criteria.
<https://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp>

Generalized Anxiety Disorder (GAD-7) Screening tool for generalized anxiety disorder.
<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/410326>

Timeline Follow Back (TLFB) Method for assessing alcohol and substance use history.
<https://arc.psych.wisc.edu/self-report/timeline-follow-back-tlfb/>

Experience Questionnaires (MEQ-30 & CEQ-7) Tools for measuring mystical and challenging aspects of the psychedelic experience.
<https://PMC5203697/> and <https://PMC5549781/>

Adverse Events (CTCAE v6.0) Standard criteria for the classification of adverse events.
<https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v6.pdf>

Harm Reduction & Education

MAPS Crisis Training (EMS) Psychedelic crisis assessment and intervention training for EMS, law enforcement and mental health providers.

<https://maps.org/course/psychedelic-training-ems/>

<https://maps.org/course/psychedelic-training-law-enforcement/>

<https://maps.org/course/psychedelic-training-mental-health/>

MAPS Crisis Training (Mental Health) Psychedelic crisis assessment and intervention training for mental health providers.

<https://maps.org/course/psychedelic-training-mental-health/>

ABCT Fact Sheets Fact sheets on psychedelic-assisted therapy from the Association for Behavioral and Cognitive Therapies.

<https://www.abct.org/fact-sheets/psychedelic-assisted-therapy/>

Coping With Post-psychedelic Difficulties A short guide for navigating and coping with difficulties after a psychedelic experience.

<https://www.dropbox.com/scl/fi/sb7ehwr161pf2rqdx07vo/SHORT-GUIDE-FOR-COPING-WITH-POST-PSYCHEDELIC-DIFFICULTIES.pdf?rlkey=d5cmbekigjuvz3b401d855kub&e=2&dl=0>

Data Collection System

Comprehensive Data Dictionary & Metrics

Demographics & Social Determinants (Part 1)

Explanation / Detail	
Patient Identifier	Anonymized unique ID.
Date of Birth	(YYYY-MM-DD) Age influences drug metabolism and cardiovascular risk. Critical for analyzing safety in older adults (End-of-Life care).
Sex at Birth	(Male / Female / Intersex) Biological sex affects pharmacokinetics.
Gender Identity	(CDC SOGI Standards) Essential for monitoring access equity for LGBTQ+ populations.
Race/Ethnicity	(OMB Standards) Mandatory to track equity access for Hispanic/Indigenous populations.
Tribal Affiliation	(Dropdown of Federally Recognized Tribes) Tracks utilization of the Equity Fund by Indigenous populations.
Household Income	(% of Federal Poverty Level [FPL]) Determines eligibility for the Treatment Equity Fund subsidy and access equity.
Veteran Status	(No / Yes: Branch) Critical for tracking PTSD outcomes in the veteran population.
Zip Code	Analyzes geographic access disparities (Rural vs. Urban access).

Clinical Baseline & History

Explanation / Detail	
Primary Diagnosis	(ICD-10 Codes) e.g. F33.2 for Major Depressive Disorder. Connects treatment to the statutory "Qualifying Condition" list.
Diagnosis Duration	(Months/Years) Differentiates acute distress from chronic/treatment-resistant conditions.
Treatment History	(Count of failed medications/therapies) Verifies "Treatment-Resistant" status (typically defined as failure of 2+ antidepressants).
Concomitant Meds	(RxNorm Codes) Tracks interactions (e.g., SSRIs, Lithium).
Baseline Severity	Validated Scale Score (e.g., MADRS, PCL-5, GAD-7, TLFB). Establishes the "before" snapshot to measure efficacy against.

Session Logistics (Part 1)

Explanation / Detail	
Patient Identifier	Linked to Demographics.
Date of Session	(YYYY-MM-DD).
Facilitator License	Links outcomes to provider performance for quality improvement.
Product Lot #	Traceability for recalls and contamination events.
Dosage	(Milligrams of Psilocybin [not biomass weight]) Medical dosing must be in mg of active molecule (e.g., 25mg).
Admin Mode	(Individual / Dyad / Group) Group therapy impacts cost and safety; data needed to evaluate relative efficacy.
Setting Type	(Clinic / Home / Retreat Center) Analyzes safety profile across different approved environments.
Mystical Experience	(MEQ-30 Score) High correlation between "mystical experience" intensity and therapeutic success.
Challenging Experience	(CEQ-7 Score) Quantifies "bad trip" aspects (paranoia, grief) to refine safety protocols.

Adverse Events (AE) Reporting

Explanation / Detail	
Session Identifier	Linked to Session.
Event Category	(Physiological / Psychological / Behavioral) Differentiates a panic attack (Psych) from hypertension (Physio).
Event Description	Detailed narrative.
Severity	Common Terminology Criteria for Adverse Events (CTCAE) v6.0 (Grades 1-5). Standard oncology/psychiatry grading.
Intervention	(Verbal De-escalation / Rescue Meds / EMS Transport) Measures the burden on emergency services. High EMS usage triggers reviews.
Suicidality	(C-SSRS Score (Post-Session)) Monitoring for treatment-emergent suicidality, a potential risk in TRD.
Duration of AE	(Minutes/Hours) Distinguishes transient distress from persistent adverse effects.

Clinical Outcomes (Follow-up)

Explanation / Detail	
Patient Identifier	Linked to Demographics.
Date of integration follow-up	(YYYY-MM-DD) Measured at intervals (such as 24 hours, 4 weeks, 3 months).
Setting Type	(Clinic / Home / Retreat Center / Virtual).
Depression Score	(MADRS or PHQ-9) Primary endpoint for TRD efficacy.
PTSD Score	(CAPS-5 or PCL-5) Primary endpoint for PTSD. PCL-5 is patient-reported and scalable.
Anxiety Score	(GAD-7) End-of-Life General Anxiety Disorder.
Substance Use	(Timeline Follow Back [TLFB] or AUDIT) Quantifies days of substance use for SUD patients.

Future Discussions

Go/No Go Checklist

Outcome Monitoring and Reporting

Emergency Preparedness and Response

Patient and Community Education

Research and Evaluation Practices