

# 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).



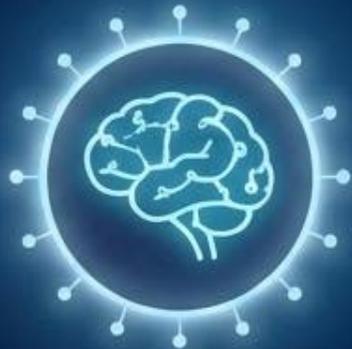
### 2. Recommend harm-reduction and quality improvement practices:

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

# RACI Norms

## Wisdom and Collaboration

Everyone has **wisdom** and that provides for the **wisest** results



- Each of us will
  - use voice and **allow others** to use voice
  - **hear others** and **be heard**
  - avoid assumptions, **ask questions**
  - reach **minimally**, act **maximally**



**Voting:** Only New Mexico residents and disclose any conflicts of interest



**Research:** we favor primary research and strive to understand biases



**Discussions:** 3 minute on-topic open mic per person with hand raised

# 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/>

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

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**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>

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**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>

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**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>

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

<https://drive.google.com/file/d/13NBY7BdAygG1TL5SOV68sl7OLi7WmkBI/view>

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

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**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-psychedelic-drug-treatment-services-standards.pdf>

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**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>

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**Colorado Ethical Code** Ethical code framework for Colorado practitioners.

[https://drive.google.com/file/d/1mlkamsv6\\_SYdml3qfHgGnuEOcvQylZxO/view](https://drive.google.com/file/d/1mlkamsv6_SYdml3qfHgGnuEOcvQylZxO/view)

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**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>

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**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>

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**Oregon Client Bill of Rights**

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

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**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-rGrOqv2AJ26jJPEdO00onA.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](https://docs.google.com/document/d/1w2Zt21sCyPWqmyEwLwnJtEurNimKIX5mpV09Uty_JNI/edit?tab=t.0)

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

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

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**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>

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

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

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**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/>

# Tools for Baselines & Follow-up

**Depression Scales (MADRS)** Montgomery–Åsberg depression rating scale for assessing depression severity.  
<https://pmc.ncbi.nlm.nih.gov/articles/PMC6878407/>

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**Patient Health Questionnaire for depression (PHQ-9)** Checklist for assessing depression-related symptoms  
<https://pmc.ncbi.nlm.nih.gov/articles/PMC1495268/>

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**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>

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

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

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

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**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/>

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**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/>

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**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=d5cmbekigiuvz3b401d855kub&e=2&dl=0>

# Patient Demographics & Social Determinants (Part 1)

Suggested user for entry: **Patient**

Some fields may be optional

Explanation / Detail	
Patient Identifier	Anonymized unique ID.
<b>Year</b> of Birth	(YYYY) 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.
<b>Diagnosed Disability</b>	(No / Yes) <b>ACLU compliance requirement.</b>
Zip Code	Analyzes geographic access disparities (Rural vs. Urban access) <b>and identifies state of which patient is a resident</b>

# Patient Clinical Baseline & History (Part 2)

Suggested user for entry: **Referring clinician**

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).
Baseline Severity	Validated Scale Score (e.g., MADRS, PCL-5, GAD-7, TLFB). Establishes the "before" snapshot to measure efficacy against.
Referral From	(primary physician, psychologist, self-referral, etc). Tracks from whom the patient was referred for psilocybin treatment
Health Assessment	(TBD). Information regarding patient medical history that would indicate they are medically cleared for treatment.

# Session Logistics (Part 1 of 2)

Suggested user for entry: **Administering clinician**

Explanation / Detail	
Patient Identifier	Linked to Demographics.
Date of Session	(YYYY-MM-DD).
Facilitator License	Links outcomes to provider performance for quality improvement.
Concomitant Medications	(RxNorm Codes) Tracks interactions (e.g., SSRIs, Lithium).
Product Lot #	Traceability for recalls and contamination events.
Dosage	(Number) Weight in mg/g of dose (this will lead to calculation of MTP)
Dosage Form	(powder, whole, capsule, troche...) To track efficacy of different methods of delivery.
Dosage Mode	(chew, tea, lemon tek) To track efficacy of different methods of delivery.
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.

# Session Logistics (Part 2 of 2)

Suggested user for entry: **Administering clinician**

Some fields may be optional

Explanation / Detail	
Prep time	(time in minutes) Time facilitator spent with patient in prior session preparation.
Time of administration	(HH:MM) The exact time the dose was ingested. Anchors the timeline.
Time of first onset	(HH:MM) The time the patient reports the <i>first</i> distinct change in perception.
Time of peak intensity	(HH:MM) Facilitator's observation or patient report of maximum effect intensity.
Time of resolution	(HH:MM) Time when the patient reports returning to functional baseline (ready for discharge).

# Challenging Events (CE) Reporting

Suggested user for entry: **Administering clinician**

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)

Suggested user for entry: **Integration clinician**

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).
Session Modality	(text). Describe types of therapeutic approaches used in follow-up integration.
Mystical Experience Score	(MEQ-30 Score) High correlation between "mystical experience" intensity and therapeutic success.
Challenging Experience Score	(CEQ-7 Score) Quantifies "bad trip" aspects (paranoia, grief) to refine safety protocols.
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.

# Medicine

Suggested user for entry: **Licensed grower**

Explanation / Detail	
Product Lot #	Traceability for recalls, contamination events, and dosage.
Psilocybin	(mg/g) Measured mg of psilocybin per gram
Psilocin	(mg/g) Measured mg of psilocin per gram
Maximum Theoretical Psilocin	(calculated) $MTP/g = Psilocin + (psilocybin * 0.719)$
Available Psilocin Fraction	(calculated) $AFP = Psilocin / MTP$
Onset Profile Category	(calculated) Rapid-onset dominant $APF \geq 0.40$ , Balanced $APF > 0.21$ and $< 0.39$ , Sustained-onset dominant $APF \leq 0.20$

To calculate the physical dose

- practitioner decides the best lot for onset profile desired
- chooses a product
- uses a calculated approach to measuring the physical dose
  - decides on the best dose: subperceptual, perceptual, high (5mg MTP to 50mg+ MTP)
  - dose weight = dose desired / MTP of product
  - record the weight