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).

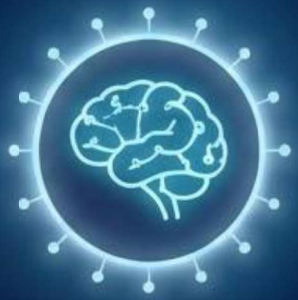
2. Recommend harm-reduction and quality improvement practices:

- 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**

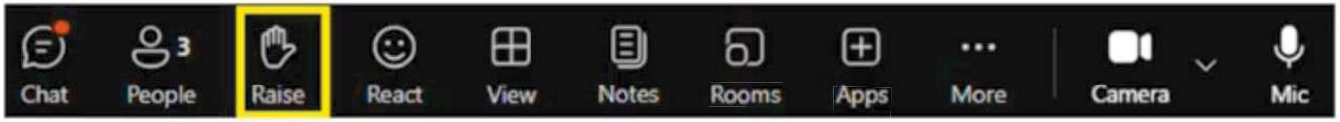
Voting: Only New Mexico residents and disclose any conflicts of interest

Research: we favor primary research and strive to understand biases

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

How to Raise your Hand in Teams

- If on a computer – click on the "hand" icon near the top of the Teams window (it says "Raise" under the icon)



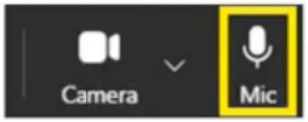
- If on the Teams app on a phone, please press the ellipses (three dots) in the menu and then the "hand" icon will appear, and you can select it

- If you are joining through voice only on a phone, press *5 to raise or lower your hand

How to Unmute/Mute in Teams

- Once your name is called, you will be able to unmute:

- To unmute/mute on Teams on a Computer or on the Teams Phone App click on the microphone icon:
  - On a computer it is in the upper right area of the Teams window.
  - On a phone it is usually in the lower left of the Teams App, however, different models of phone (Apple, Android, etc…) may have the mute/unmute icon in a different location:



- Telephone: voice only - press *6 to unmute/mute

Program and Board Information

- Email: Medical.Psilocybin@doh.nm.gov
- Program Website:
  https://www.nmhealth.org/about/mcpp/mpp/
- Advisory Board Website:
  https://www.nmhealth.org/about/mcpp/mpp/mpab/

Workgroup 3:
Data and Reporting Architecture

Core / Extended Data Set Framework

Participant baseline data

- age
- race / ethnicity
- tribal affiliation if voluntarily disclosed
- gender identity
- sexual orientation
- primary language
- disability / accessibility needs
- ZIP code or region
- presenting condition / reason for seeking services
- relevant medical history
- relevant psychiatric history
- trauma history if clinically relevant and voluntarily disclosed
- substance use history if relevant
- current medications
- known contraindications / risk flags
- referral source
- prior psychedelic experience

Preparation data

- number of preparation sessions
- readiness assessment completed
- informed consent completed
- medication interaction review completed
- risk screening completed
- support plan documented
- participant preferences documented
- cultural / accessibility needs documented
- exclusion / deferral decision and reason category

Service episode data

- date of session
- site / location type
- facilitator role(s)
- therapist / supervisor involvement if applicable
- product type
- dose
- session length
- protocol deviations
- significant in-session events
- challenging experience yes/no
- adverse event yes/no
- emergency intervention yes/no

Adverse event / incident data

- event type
- timing
- severity
- duration
- response taken
- EMS / hospitalization / law enforcement involvement
- event resolved
- follow-up required

Integration / follow-up data

- number of integration sessions
- follow-up completed yes/no
- unresolved distress yes/no
- referrals made
- functional status change
- symptom change measure if adopted
- dropout / lost to follow-up

Participant experience / feedback data

- felt physically safe
- felt emotionally safe
- felt respected
- care matched preferences
- cultural / spiritual fit
- concerns about provider behavior
- concerns about setting
- satisfaction with preparation
- satisfaction with session
- satisfaction with integration
- would recommend / would choose again

Program-level quality data

- total participants served
- completion rate
- dropout rate
- frequency of challenging experiences
- frequency of adverse events
- serious adverse event rate
- emergency transfer rate
- participant satisfaction trends
- disparities by population group
- site-level variation
- common reasons for complaints or incidents
- rates of deferral / exclusion
- patterns in medication interaction flags
- complaints tied to consent or education gaps
- disparities in participant-reported safety / respect / fit

Core vs extended structure

This group should formally distinguish:

- **Required minimum data elements**
- **Recommended enhanced data elements**

Workgroup 1:
Care Pathway and Safety

Core / Extended Data Set Framework

This group identifies safety-related fields needed in the data model, such as:

- known contraindications / risk flags
- current medications
- readiness assessment completed
- medication interaction review completed
- risk screening completed
- support plan documented
- date of session
- site / location type
- facilitator role
- dose
- session length
- protocol deviations
- significant in-session events
- challenging experience yes/no
- adverse event yes/no
- emergency intervention yes/no
- event type
- timing
- severity
- duration
- response taken
- EMS / hospitalization / law enforcement involvement
- event resolved
- follow-up required
- unresolved distress
- referrals made
- dropout / lost to follow-up

Workgroup 2:
Participant Experience and Fit

Core / Extended Data Set Framework

This group identifies fit/experience-related fields, such as:

- participant goals
- participant preferences and boundaries
- spiritual / religious / cultural considerations identified
- cultural / accessibility needs documented
- whether participant preferences were followed
- whether optional practices were used
- whether event may involve:
  - boundary issue
  - cultural / spiritual mismatch
  - consent concern
  - facilitator conduct concern
- participant-reported benefit
- participant-reported harm
- felt physically safe
- felt emotionally safe
- felt respected
- care matched preferences
- cultural / spiritual fit
- concerns about provider behavior
- concerns about setting
- satisfaction with preparation
- satisfaction with session
- satisfaction with integration
- would recommend / would choose again
- race / ethnicity
- tribal affiliation if voluntarily disclosed
- language
- disability / accessibility needs
- accommodations requested / provided
- participant-reported cultural or spiritual mismatch

Aug 7 9am-11am –

Core/Extended Dataset Framework Consensus