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**

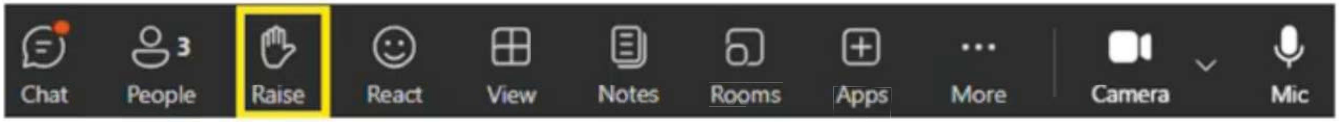
Voting: Only New Mexico residents and disclose any conflicts of interest

Research: we favor primary research and strive to understand biases

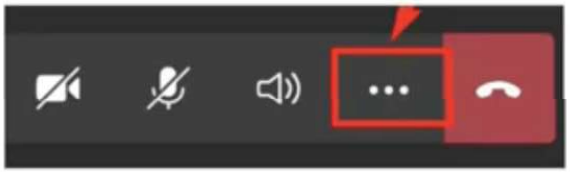
Discussions: 3 minute on-topic open mic per person with hand raised

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

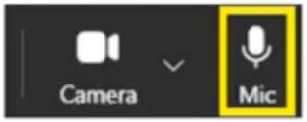


- If you are joining through voice only on a phone, press *5 to raise or lower your hand

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/

TRUST BY DESIGN

Data Governance, De-identification & Responsible Use in Psychedelic Medicine

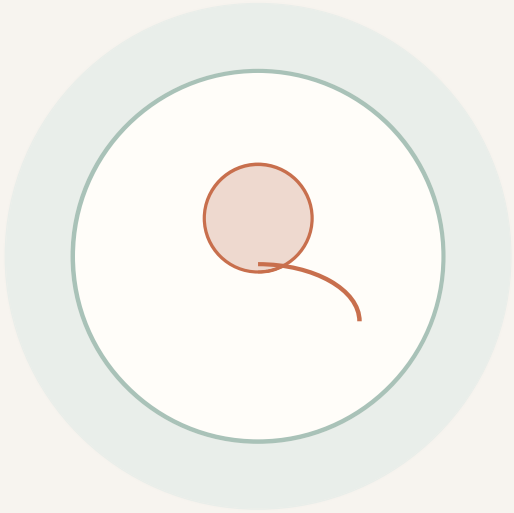
Nathan Oakes – ENFAM Labs

Research and Continuous Improvement Committee for the New Mexico Psilocybin Medicine Advisory Board
August 7, 2026

A policy framework for protecting people while preserving the value of data.

01 • HUMAN STAKES

Why Data Trust Matters Here



THE PERSON
AT THE CENTER

Psychedelic medicine can involve unusually intimate information.

Trauma • mental health • substance use • diagnoses • medications • altered-state experiences • adverse events • personal narrative

If people do not trust the data system, some may not seek care.

Trust is part of the safety model.

02 • THE DATA LANDSCAPE

Today's Data — and Tomorrow's

CLINICAL

- Diagnoses
- Medications
- Outcomes
- Adverse events

EXPERIENTIAL

- Narrative
- Session notes
- Audio / video
- Context

EMERGING

- Wearables / biometrics
- Neurophysiology
- Immersive telemetry
- AI-derived inferences

Rules should be resilient to data types that do not yet exist.

Collect intentionally. Expose minimally. Use purposefully.

03 • WORKING VOCABULARY

De-identification Is Not Binary

Working definitions for this talk; legal and technical definitions vary by context.

Risk depends on what remains in the data — and what it can be linked to.

De-identification is risk management, not a magic switch.

04 • QUASI-IDENTIFIERS

You Don’t Need a Name to Know Who Someone Is

A FICTIONAL RECORD

Age range	**65–69**
Community	**Small / distinctive**
Diagnosis	**Uncommon**
Treatment timing	**Specific date**
Event	**Rare outcome**

No name.
No SSN.
Still identifiable.

Quasi-identifiers become identifying in combination — especially in small or distinctive populations.

Small or distinctive populations need stronger disclosure controls.

05 • THREE LENSES

Security, Privacy & Governance Are Different Problems

01 SECURITY

Who can get to it?

02 PRIVACY

What can it reveal?

03 GOVERNANCE

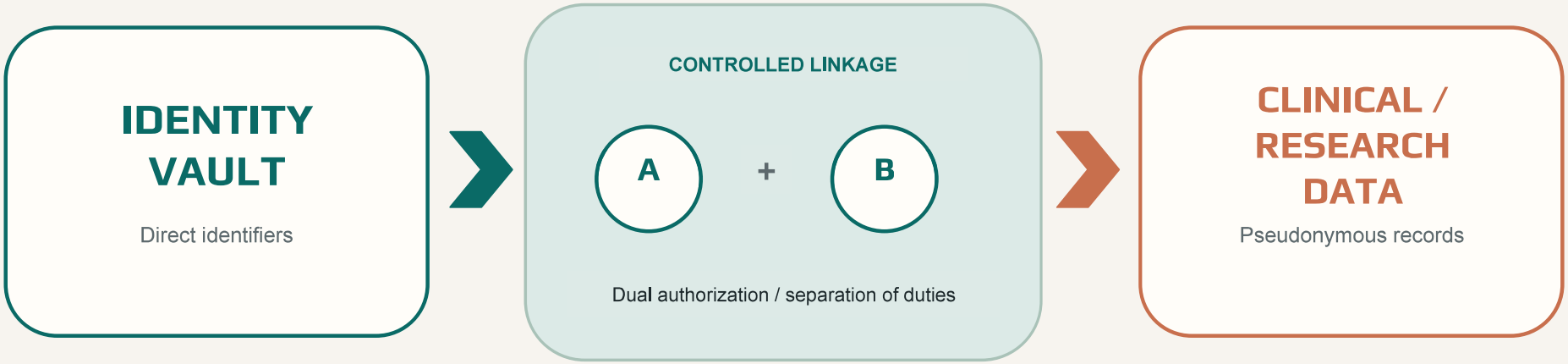
What is allowed?

A system can be secure and still use data in ways patients never expected.

06 • CONTROLLED RE-LINKING

Re-identification Must Be Exceptional and Governed

ILLUSTRATIVE PATTERN — NOT A PRESCRIBED ARCHITECTURE



JUSTIFIED | AUTHORIZED | LOGGED | AUDITABLE

The ability to re-identify may be necessary. That does not mean it should be easy.

07 • ETHICAL CENTER

Patient Data Should Serve the Patient

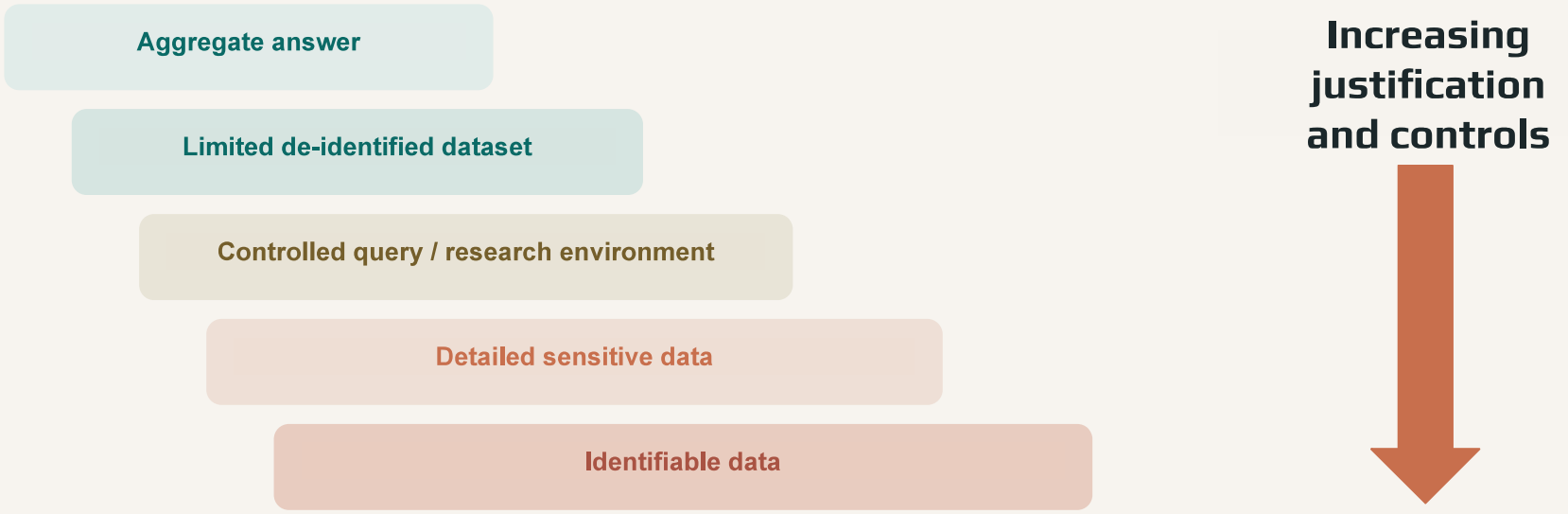
- Purpose limitation
- Plain-language transparency
- Meaningful patient control
- Access, correction & appropriate deletion
- No sale, brokerage or exploitation

Patient-level information collected through participation in the Medical Psilocybin Program should not become a commercial data asset.

The patient's intimate information should never become the product.

08 • PROGRESSIVE DISCLOSURE

Enable Research Without Exposing People



Use the least identifying form of data that can answer the legitimate question.

09 • POLICY QUESTIONS

What New Mexico Should Define Now

01 Permitted purposes

02 Prohibited uses

03 Data crossing each boundary

04 Re-identification rules

05 Auditability requirements

06 Downstream obligations

07 Patient rights & explanations

08 Periodic review

Policy defines the boundaries technology must enforce.

Protect the person.

Protect the data.

Preserve the value.

Good governance makes responsible innovation possible.

Q&A

Working Glossary

Identified

Data directly linked to a specific person through explicit identifiers or context.

Pseudonymized / re-linkable

Direct identifiers are replaced or separated, but an authorized mechanism can reconnect identity.

De-identified

Identification risk has been deliberately reduced to an agreed level; risk is not necessarily zero.

Aggregated

Information reported at a group level rather than as individual-level records; small cells may still create risk.

Anonymized

Working definition here: no reasonable mechanism remains to re-link the information to a person.

Quasi-identifier

An attribute that may not identify someone alone but can become identifying when combined with other data.

Re-identification

Reconnecting identity to data that had been separated, pseudonymized or otherwise de-identified.

Progressive disclosure

Providing the least identifying form of information capable of answering the legitimate question.

These are practical working definitions for this presentation; legal and technical definitions should be defined explicitly in the program's rules.

REFERENCE

REFERENCE / BACKUP

Quasi-identifiers & Disclosure Risk

Do not rely on a static list of “safe” and “unsafe” fields.

SENSITIVITY	How harmful could disclosure be?
GRANULARITY	How specific are dates, locations, ages or categories?
POPULATION UNIQUENESS	How many people plausibly match the combination?
LINKABILITY	Can records be linked across datasets or over time?
EXTERNAL AVAILABILITY	What public or commercial data could an attacker combine with it?

TEST THE RELEASE

“Given this proposed dataset and reasonably available outside information, how successfully could someone figure out who these people are?”

Re-identification / disclosure-risk testing

REFERENCE

REFERENCE / BACKUP

Illustrative Re-identification Controls

1. **Request** — Defined purpose + minimum necessary data
2. **Authorize** — Appropriate role; dual approval for high-risk events
3. **Re-link** — Dedicated controlled mechanism; no ad-hoc joins
4. **Record** — Immutable reason, requester, approver, scope and time
5. **Review** — Audit; exceptional events may require state reporting

Possible legitimate categories

- **Patient-directed**
- **Safety / continuity of care**
- **Legal / regulatory**
- **Exceptional authorized research**

Emergency “break-glass” access can exist — but the break should be unavoidable in the audit trail.

REFERENCE

REFERENCE / BACKUP

Selected Standards & Resources

NIST SP 800-188 — De-Identifying Government Datasets: Techniques and Governance

https://csrc.nist.gov/pubs/sp/800/188/final

NISTIR 8053 — De-Identification of Personal Information

https://csrc.nist.gov/pubs/ir/8053/final

NIST SP 800-226 — Guidelines for Evaluating Differential Privacy Guarantees

https://csrc.nist.gov/pubs/sp/800/226/final

NIST Privacy Engineering Resources / Privacy Risk Assessment Methodology (PRAM)

https://www.nist.gov/itl/applied-cybersecurity/privacy-engineering/resources

BASELINES — NOT THE POLICY

ISO/IEC 27001

Information-security management system

ISO/IEC 27701:2025

Privacy information management system (PIMS)

SOC 2

Attestation against AICPA Trust Services Criteria

These can demonstrate maturity. They do not decide what New Mexico should permit organizations to do with patient data.

ISO/IEC 27701:2025: https://www.iso.org/standard/27701

Research and Continuous Improvement

Reporting Framework Task Breakdown

Workgroup 1: Care Pathway and Safety

- reporting points across the care pathway:
  - pre-session / preparation report
  - session report
  - integration / post-session report
  - escalation / incident report
- **event tiers:**
  - **Tier 1 routine / no incident**
  - **Tier 2 challenging experience requiring added support**
  - **Tier 3 adverse event with clinical significance**
  - **Tier 4 serious adverse event requiring external response or formal review**
- **review process:**
  - **routine review monthly**
  - **Tier 3–4 prompt review**
  - **quarterly trend review**
  - **feedback into safety protocols and standards updates**

Workgroup 2: Participant Experience and Fit

- participant feedback report, including:
  - felt safe / respected
  - care matched stated preferences
  - concerns about provider behavior
  - cultural or spiritual mismatch
  - perceived harms or benefits
  - satisfaction with preparation, session, and integration
- input into pre-session reporting:
  - participant goals
  - participant preferences and boundaries
  - cultural / spiritual / accessibility considerations identified
- input into session reporting:
  - whether participant preferences were followed
  - boundary concerns
- input into post-session reporting:
  - participant-reported concerns

Workgroup 3: Data and Reporting Architecture

- defines:
  - what gets documented
  - when
  - by whom
  - how it is reviewed
- structures reporting into:
  - pre-session / preparation report
  - session report
  - integration / post-session report
  - participant feedback report
  - escalation / incident report
- defines workflow responsibilities
- supports event tier logic and review timing
- documentation requirements for consent, education, screening, and medication review
- workflow responsibilities for who captures which safety and equity-related fields
- escalation pathways for issues involving cultural mismatch, consent concerns, or screening failures

Research and Continuous Improvement

Harm-Reduction / QI Framework Task Breakdown

Workgroup 1:
Care Pathway and Safety

- screening and readiness safeguards
- preparation safeguards
- session safeguards
- integration safeguards
- system-learning questions such as:
  - Are certain harms happening repeatedly?
  - Are emergency transfers clustered in certain settings?
  - Are consent and prep reducing preventable distress?
- sample QI actions:
  - update screening guidance
  - adjust emergency preparedness standards
  - change documentation requirements
  - flag issues to other committees
- **event tiers:**
  - **Tier 1 routine / no incident**
  - **Tier 2 challenging experience requiring added support**
  - **Tier 3 adverse event with clinical significance**
  - **Tier 4 serious adverse event requiring external response or formal review**
- **review process:**
  - **routine review monthly**
  - **Tier 3–4 prompt review**
  - **quarterly trend review**
  - **feedback into safety protocols and standards updates**

Workgroup 2:
Participant Experience and Fit

- participant-centered preparation safeguards:
  - preferences and boundaries asked explicitly
  - optional vs non-optional elements made clear
- session safeguards:
  - respect for participant boundaries
  - non-imposition of facilitator beliefs
- integration safeguards:
  - participants have a way to report concerns afterward
- QI questions such as:
  - Are participants reporting that preferences were ignored?
  - Are certain groups reporting poorer fit or worse outcomes?
  - Are there patterns of cultural/spiritual mismatch?
- sample QI actions:
  - revise consent content
  - recommend facilitator training
  - flag issues for equity, training, or clinical practice committees
  - identify indicators of cultural, spiritual, or participant-provider mismatch
  - recommend participant-reported measures related to respect, safety, fit, and cultural responsiveness
  - identify patterns that should trigger referral to the Equity, Access, and Cultural Considerations Committee

Workgroup 3:
Data and Reporting Architecture

- determines what can be monitored reliably across sites
- translates safeguards into trackable indicators
- defines what should be aggregated for QI review:
  - adverse event patterns
  - challenging experience patterns
  - participant complaints
  - dropout rates
  - preference mismatch trends
  - disparities across participant groups
  - site-to-site variation

Workgroup 1:
Care Pathway and Safety

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

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

Research and Continuous Improvement

Core / Extended Data Set Framework Task Breakdown

Sept 11 9am-11am –

Core/Extended Dataset Framework Consensus

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**