



RAPC

RESEARCH ADVISORY
PANEL OF CALIFORNIA

2025

55th Annual Report
to the Governor and
Legislature of California

Research Advisory Panel of California
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This report represents a consensus among Panel members acting as individual experts. It does not represent policies or positions of the appointing agencies, nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

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RESEARCH ADVISORY PANEL OF CALIFORNIA

LEGISLATIVE MANDATE

California law, pursuant to Health and Safety Code Sections 11480 and 11481,⁽¹⁾ requires proposed research studies using certain opioid, stimulant, and hallucinogenic drugs classified as schedule I and schedule II controlled substances, cannabis, and research projects involving the treatment of substance use disorders utilizing any drug, scheduled or not, to be reviewed and authorized by the Research Advisory Panel of California (RAPC).

RAPC primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the studies. Panel members evaluate the scientific validity of each proposed project and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risks of research.

Health and Safety Code Section 11481 provides that RAPC “shall, annually and in the manner determined by the panel, report to the Legislature and the Governor those research projects approved by the panel, the nature of each research project, and where available, the conclusions of the research project.” This report is submitted pursuant to that requirement.

(1) RAPC activities in 2025 are based on statutory requirements in effect from January 1 through December 31, 2025. Activities implementing statutory requirements effective January 1, 2026 will be reflected in the annual report covering the reporting period January 1, 2026, through December 31, 2026.

RESEARCH ADVISORY PANEL OF CALIFORNIA

2025 PANEL MEMBERS

RAPC consists of members appointed by (a) the University of California; (b) a statewide medical society designated by the Governor; (c) a private university designated by the Governor; (d) the California State Board of Pharmacy; (e) the Department of Public Health; (f) the Attorney General; and (g) the Governor. Members of RAPC serve without compensation. RAPC's staff consists of the Executive Officer, to carry out its day-to-day operations.

Jennifer Mitchell, PhD

Panel Chair

Professor of Neurology and Psychiatry and Behavioral Sciences, University of California, San Francisco (UCSF) School of Medicine, and Associate Chief of Staff for Research and Development, San Francisco Veterans Administration Medical Center (SFVAMC)

Appointed by the Governor

Judy Aoyagi, PharmD

Senior Pharmaceutical Consultant II, Specialist

Center for Preparedness and Response, California Department of Public Health

California Public Health Officer Designee

Appointed by the Public Health Officer

(Term started November 14, 2025)

Martine D'Agostino

Deputy Attorney General, State of California Office of the Attorney General, Oakland

Appointed by the California Attorney General

James J. Gasper, PharmD, BCPP

Psychiatric and Substance Use Disorder Pharmacist,

California Department of Health Care Services

Appointed by the California Department of Public Health

Boris Heifets, MD, PhD

Associate Professor of Anesthesiology, Perioperative and Pain Medicine,

and by courtesy, Psychiatry and Behavioral Sciences, Stanford University School of Medicine

Appointed by Stanford University

Kelly C. Lee, PharmD, MAS, BCPP, FCCP, FASHP

Professor of Clinical Pharmacy, Associate Dean for Assessment and Accreditation,

Director, PGY2 Residency in Psychiatric Pharmacy, University of California, San Diego

Appointed by the California State Board of Pharmacy

Daniele Piomelli, PhD

Distinguished Professor, University of California, Irvine School of Medicine
Director, Center for the Study of Cannabis
Appointed by the University of California

Cyrus Rangan, MD, FAAP, FACMT

Toxicologist and Assistant Deputy Director, Center for Healthy Communities California
Department of Public Health
Designee for the Public Health Officer
(Term ended on September 25, 2025)

RAPC Staff

Tanveer Khan, PharmD

Executive Officer
Appointed by the California Attorney General

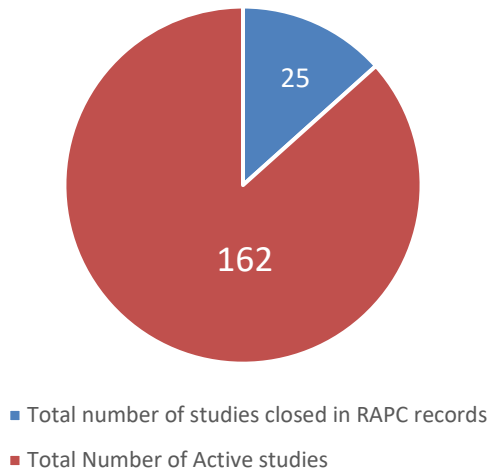
2025 SUMMARY OF ACTIVITIES

During 2025 (Jan. 1 – Dec. 31, 2025), the Research Advisory Panel of California (RAPC) approved a total of 30 new study applications and 57 amended applications (some studies were amended multiple times in 2025). The 30 new studies consisted of six multi-site studies, five academic human studies, 18 non-human studies, and one controlled substance use disorder treatment study. Twenty-five studies were completed or terminated and closed in RAPC records. [Assembly Bill 1103 \(Ward\)](#) was approved on October 10, 2025, but its contents are not reflected in the activities of 2025 because that legislation took effect on January 1, 2026, after the close of this reporting period.

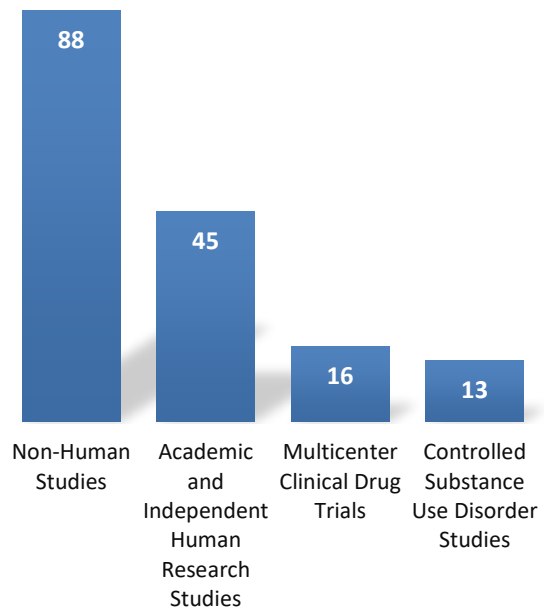
Table 1 in this report lists the new studies approved in 2025. Table 2 lists amended studies approved in 2025. Table 3 lists the 25 studies completed or terminated in 2025 and closed in RAPC files. At the end of 2025, RAPC was monitoring 162 active studies (see Figure 1). See Appendices A, B, C, and D for specific listings (for a breakdown, see Figure 2).

As part of RAPC's supervisory responsibilities, ongoing projects are monitored by means of annual progress reports, serious adverse event reports, and site visits. RAPC did not conduct site visits in 2025. RAPC approval may be withdrawn if study activities deviate substantively from the approved protocol or conditions of Panel approval are not met.

2025 ACTIVE AND CLOSED STUDIES (Fig. 1)



2025 ACTIVE STUDIES BY TYPE (Fig 2)



SELECTED RESEARCH FINDINGS

Below are brief summaries of several RAPC-approved projects that are indicative of the types of controlled substance research currently ongoing in California.

LITES Clinical Trial Manager Rachel Molinaro, MEd, BS, CCRC and colleagues at the University of Pittsburg are conducting a multisite clinical trial with sites in California entitled: *"Prehospital Analgesia INtervention trial (PAIN)."* The Linking Investigations in Trauma and Emergency Services (LITES) team provided the following summary of this research:

Prehospital pain management following traumatic injury is an ethical and operational necessity. Effective analgesia in the field is necessary to facilitate lifesaving interventions for injured patients. Currently, opioid treatments, including fentanyl, are common but can result in hemodynamic instability, respiratory depression, and risk of misuse. In injured patients with compensated shock, the detrimental effects of necessary pain treatment are magnified and may be associated with higher risk of mortality. Low dose ketamine (for pain) is an effective alternative therapy and is associated with low incidence of hemodynamic instability and respiratory depression. Due to confounding by indication and selection biases associated with using available prehospital data, only a randomized trial can determine the safety and effectiveness of these pain management interventions. The objective of the Prehospital Analgesia INtervention (PAIN) trial is to perform a prospective, interventional, randomized trial among prehospital trauma patients with compensated shock and an indication for pain management, comparing patient centered outcomes following prehospital administration of ketamine hydrochloride versus fentanyl citrate.

Dr. Trisha Suppes, MD, PhD and colleagues at the Veterans Administration (VA) Palo Alto are conducting human research entitled: *"A Randomized Trial to Compare MDMA-assisted Cognitive Processing Therapy (aCPT) Versus a VA Standard-of-care CPT for the Treatment of Severe Posttraumatic Stress Disorder among Veterans."* Dr. Suppes provided the following abstract of this research:

This study is the first in the United States to pilot an MDMA*-assisted version of Cognitive Processing Therapy. Cognitive Processing Therapy (CPT) is a gold-standard treatment in the Veterans Affairs Health Care System to treat Veterans with PTSD. This study will provide a head-to-head comparison of standard CPT with MDMA-assisted CPT. Prior studies have traditionally paired MDMA therapy with unstructured therapies which have not been independently evaluated for efficacy in randomized trials. Furthermore, this is one of the first MDMA studies in the Veteran population and may help inform the feasibility of implementing psychedelic-assisted treatments in the VA Health Care System.

(*MDMA = 3,4,-methylenedioxyamphetamine)

Dr. Timothy Furnish, MD and colleagues at the University of California San Diego are conducting human research entitled “*Behavioral and Neural Mechanisms Supporting Psilocybin assisted therapy for Phantom Limb Pain.*” Dr. Furnish provided the following summary of this research:

Approximately 50–80% of amputees experience intractable phantom limb pain, which is a debilitating pain condition caused by a complex interplay between sensory, cognitive, and affective neural processes. Converging lines of evidence suggest that classical/serotonergic psychedelics including lysergic acid diethylamide (LSD) and psilocybin can reduce phantom limb pain. For example, early studies demonstrated relief of phantom limb pain following treatment with LSD and a recent case study found similar results in an individual with phantom limb pain who self-administered. A new wave of clinical trials has established classical psychedelics as effective treatments for health conditions such as depression, and substance abuse problems, and relief of pain and psychological distress in cancer patients following treatment with LSD has been observed. However, the neural mechanisms related to psychedelic induced pain relief remain unclear.

Psychedelics have been proposed to “reset” neurofunctional connections in the brain which have been found to be aberrant in phantom limb pain. Moreover, serotonergic psychedelics have been found to decrease sensorimotor network connectivity and overrepresentation of the phantom in sensorimotor areas corresponds positively with pain in phantom limb patients. Despite these observations, no study to date has investigated the effect of psilocybin on pain experience and the underlying neural mechanisms in phantom limb pain patients. To bridge these gaps, our double-blind, randomized, placebo-controlled studies will employ functional magnetic resonance imaging (fMRI), psychophysical (i.e., psychological evaluation of physical processes) pain testing, and a battery of surveys investigating pain-health outcomes, prior to and following administration of psilocybin in phantom limb patients.

Dr. Ryan D. Baxter, PhD and colleagues at the University of California, Merced are conducting non-human research entitled: “*Light Control and Oxidation Potential of Cannabinoids.*” Dr. Baxter provided the following summary of this research:

Endothelial dysfunction and compromised vascular integrity are major contributors to the onset and progression of diverse chronic diseases, including cardiovascular disease, diabetes, stroke, dementia, and cancer. These pathologies are further exacerbated in aging populations, where endothelial cells (ECs) exhibit reduced viability, increased inflammatory signaling, and diminished barrier function. Cannabinoids—including psychoactive Δ^9 -tetrahydrocannabinol (THC), non-psychoactive cannabidiol (CBD), and synthetic analogues—are widely used for therapeutic and recreational purposes. Yet, their impact on endothelial health and vascular homeostasis remains poorly defined, particularly within physiologically relevant microenvironments that reflect age-related tissue changes.

Recent findings by our team demonstrate that low-dose CBD ($\sim 4 \mu\text{M}$) promotes endothelial viability, while higher doses are cytotoxic to the same cells. Importantly, we found that biological activity is strongly dependent on cannabinoid structure. CBD-like synthetic analogues showed variable effects, suggesting a critical opportunity to optimize molecular design for vascular protection. Building on this foundation, we propose a multidisciplinary

investigation into how cannabinoids and their synthetic derivatives influence endothelial function across aging-relevant vascular contexts.

Dr. Suzaynn Schick, PhD and colleagues at the University of California, San Francisco are conducting non-human research entitled: *“Measuring Environmental Tobacco and Cannabis: Pollutants and Exposures.”* Dr. Schick provided the following summary of this research:

The Schick Laboratory studies the chemistry and toxicity of secondhand cannabis smoke. Research has shown that smoke from tobacco and from wood change chemically after they are released into the air. Our previous research has shown that cigarette smoke becomes more toxic over time and that nicotine and the tobacco-specific nitrosamine NNK** stick to indoor surfaces and linger for months. We are creating cannabis smoke under controlled conditions in the laboratory to see how it changes when it is diluted into room air and interacts with the chemicals that are normally present in the air and on surfaces indoors.

(**NNK = 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone)

Dr. Paul F. Daley, PhD and colleagues at the Alexander Shulgin Research Institute (ASRI) are conducting non-human research entitled: *“Synthesis and structure-activity relationships of hallucinogenic drugs acting on biogenic amine systems.”* Dr. Daley provided the following summary of this research:

Our company continues to build on previous small molecule discoveries, by synthesizing additional new compounds covered by our patents, and advancing a lead short-acting tryptamine toward clinical trials. We made an unexpected discovery while designing and characterizing a new molecule type, originally intended to allow duration control for psychedelic compounds. Evaluating a prototype molecule, dubbed “XOB,” we found it was not a functional psychedelic, but instead exhibited a dual antagonist action at serotonin 2A and voltage gated sodium channels. Some neurological diseases, including bipolar disorder, are already treated with antagonist drugs targeting these receptors; this new compound class offers the possibility of reducing the number of medications treating these disease states, improving clinical management for patients.

Dr. Michael Silver, PhD and colleagues at University of California, Berkeley, are conducting human research entitled: *“Investigating the Persisting Effects of a Single Dose of Psilocybin on Structural Plasticity in Healthy Older Adults.”* Dr. Silver has provided the following summary of this research:

We will use cognitive exams, perceptual tasks, brain imaging, peripheral psychophysiology, and surveys to investigate the persisting effects of a moderate-to-high dose of psilocybin on cognition, predictive coding, and affect in healthy older adults. We will assess changes in these measures by comparing baseline to one-week and one-month post-treatment. This study will be conducted in participants with no diagnosable mental health conditions, but

the resulting mechanistic insights may inform development of treatments that use psychedelics to help individuals shift from pathological patterns of thought, emotion, and behavior to more healthy and adaptive ones. This information will be crucial for designing and optimizing mental health treatments using psychedelic agents.

Furthermore, these studies may also reveal biomarkers that can then be used to predict the likelihood of a patient's response to a particular type of therapeutic intervention. This study will include healthy older adults (60-85 years old), allowing us to characterize effects of psilocybin from the acute subjective experience to long-term persisting effects, in old age. Studying the effects of psilocybin in old age may inform the development of treatments that use psychedelics to improve cognition and affect in older adults by promoting brain changes that oppose the effects of synaptic dysfunction in aging and neurodegeneration in Alzheimer's disease.

TABLE 1

RESEARCH STUDIES APPROVED IN 2025

University of Cincinnati, NIDA | Cincinnati, OH

Evaluation of Tirzepatide as an Adjunct to Buprenorphine for the Treatment of Opioid Use Disorder: A Pragmatic, Multisite, Double-Blind, Randomized, Placebo-Controlled, Trial. (TAB Trial, CTN-0152)

Alexander Chen, MD | University of Southern California | Los Angeles, CA

Use of Single-Dose Pre-operative Oral Methadone for Pain Management in Outpatient Arthroscopic Hip and Knee Procedures

Daniel Tsze, MD, MPH | Columbia University | New York, NY

Efficacy of Intravenous Sub-Dissociative Ketamine Versus Intravenous Morphine in Children with Acute Pain (MoKA)

Cybin IRL Limited | CRO: Worldwide Clinical Trials | Dublin, Ireland

A Phase III Long-Term Extension Trial with Optional Additional Doses of CYB003 to Assess the Safety and Long-Term Efficacy in Participants with Major Depressive Disorder (EXTEND)

Cybin IRL Limited | CRO: Worldwide Clinical Trials | Dublin, Ireland

An Efficacy and Safety, Phase III, Multi-center, Double-Blind, Randomized Controlled Study Comparing 2 Active Doses of CYB003 and Placebo in Eligible Participants with Major Depressive Disorder (EMBRACE)

Definium Therapeutics US (previously Mind Medicine, Inc.) | New York, NY

A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, 12-week study (Part A) with a 40-week Open-label Extension (Part b) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Major Depressive Disorder (EMERGE)

Gul Dolen, MD, PhD | University of California, Berkeley | Berkeley, CA

Molecular, Synaptic and Circuit Mechanisms Underlying Social Cognition and Reward in Health and Disease

Xiaomin Cathy Gong, PhD | Diazyme Laboratories, Inc. | Poway, CA

γ -Hydroxybutyric Acid (GHB) Assay or γ -Hydroxybutyrate (GHB) Assay

Christopher Hamad, MD | University of California, Los Angeles | Los Angeles, CA

The Impact of Cannabis Exposure on Fracture Healing and Antimicrobial Immune Function in a Murine Model

Richard T. Lee, MD | City of Hope National Medical Center | Irvine, CA

A Pilot Study to Evaluate the Benefits of Phytocannabinoids for the Treatment of Chronic Chemotherapy-Induced Peripheral Neuropathy

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Multi-omic Characterization of the Effects of Psychedelic Drugs on the CNS

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Investigating the Neuroimmunomodulatory Properties of Psilocybin.

Stephen Mahler, PhD | University of California, Irvine | Irvine, CA

Neural Circuits Underlying Heroin Motivation and Addiction

David Olson, PhD | University of California, Davis | Davis, CA

Chemical Modulation of Neural Plasticity, Learning and Memory (2)

Susan Powell, PhD | Veterans Affairs San Diego Healthcare System | San Diego, CA

Preclinical Neuropsychopharmacology of Psychoactive Substances

Ranmal Samarasinghe, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Exploring the Differential Brain Network Electrodynamics and Cellular Impacts of Psilocybin and MDMA Versus SSRIs Using Human Brain Organoids

Michael Taffe, PhD | University of California, San Diego | La Jolla, CA

Panel Approved Research Study (1)

Michael Taffe, PhD | University of California, San Diego | La Jolla, CA

Panel Approved Research Study (2)

Transcend Therapeutics | New York, NY

An Evaluation of the Safety and Efficacy of Methylone for the Treatment of PTSD IMPACT-2 (Investigation of Methylone for Post-Traumatic Stress Disorder [PTSD]) (IMPACT-2)

Transcend Therapeutics | New York, NY

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of TSND-201 for the Treatment of PTSD

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

Assessment of Changes in Behavioral and Neural Correlates of Social Processing Produced By 3,4-Methylenedioxymethamphetamine (MDMA)

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

Assessment of Changes in Behavioral and Neural Correlates of Self- Versus Other- Processing Produced By N,N-dimethyltryptamine (DMT)

Aaron Vollrath, PhD | Lin-Zhi International, Inc. | Santa Clara, CA

Cross-Reactivity Characterization of LSD, LSD Metabolites, and Lysergamide Analogs for Homogeneous Immunoassay Development

Aaron Vollrath, PhD | Lin-Zhi International, Inc. | Santa Clara, CA

Lin-Zhi Nitazene Immunoassay Development Study

Cory Weissman, MD, PhD | UC San Diego Department of Psychiatry | La Jolla, CA

Psilocybin-Assisted Therapy for Physician Well-Being and Burnout: Feasibility, Safety, Clinical Effectiveness and Biomarkers of Response [PAT-B (Psilocybin-Assisted Therapy for Physician Well-Being and Burnout)])

Marc Weitraub, PhD | University of California, Los Angeles | Los Angeles, CA

Group Psilocybin-Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

Audrey Williams, PhD | Lawrence Livermore National Laboratory | Livermore, CA

Illicit Cannabis Cultivation in California: Illegal Pesticides and Risks to Human Health (IMPACT-2)

Joshua Woolley, MD, PhD / Prasad Shirvalkar, MD, PhD | University of California, San Francisco | San Francisco, CA

PINS: Psilocybin with Intracranial Neural Sensing (PINS)

Li Ye, PhD | The Scripps Research Institute | La Jolla, CA

A Novel Strategy Toward Spatially Resolved Pharmacology

Natalie Zlebnik, PhD | University of California, Riverside | Riverside, CA

Therapeutic Potential of Cannabinoids for Cocaine Relapse

TABLE 2

RESEARCH STUDIES AMENDED IN 2025

Atai Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial to Assess the Efficacy, Safety, and Tolerability of Repeated Doses of VLS-01 Buccal Film in Participants with Treatment Resistant Depression

Beckley Psytech Ltd. | CRO: Worldwide Clinical Trials Limited | Nottingham, UK

A Quadruple Masked, Dose-Finding Study to Evaluate the Efficacy and Safety of Intranasal BPL-003 in Patients with Treatment-Resistant Depression. (CORE Study)

Braeburn, Inc. | CRO: Lotus Clinical Research | Plymouth Meeting, PA

A Phase I, Open-Label Study to Demonstrate Bioequivalence Between Two Different Manufacturers of CAM2038 (Weekly) and CAM 2038 (Monthly) 128mg in Adult Patients with Opioid Use Disorder

Baruch Rael Cahn, MD, PhD | University of Southern California (USC) | Los Angeles, CA

An Exploratory Study of Feasibility, Efficacy, and Mechanisms of Mindfulness-Assisted Psychedelic Therapy

Robin Carhart-Harris, PhD | University of California, San Francisco | San Francisco, CA

2 x 2 Factorial, Double-Blind, Randomized Study of ‘Set and Setting’: A Translational Study in Healthy Volunteers (Set and Setting study [S&S])

Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Morrisville, NC

A Phase II, Multicentre, Randomised, Double-Blind, Controlled Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of COMP360 in Participants with Recurrent Major Depressive Disorder

Compass Pathfinder Limited | CRO: ICON plc | Cheshire, UK

A Phase III, Multicentre, Randomised, Double-Blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants with Treatment-Resistant Depression (COMP 006)

Compass Pathfinder Limited | CRO: ICON plc | Cheshire, UK

A Phase III, Multi-Centre, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy, Safety, and Tolerability of a Single Administration of COMP360 in Participants with Treatment-Resistant Depression

Natasia Courchesne-Krak PhD | CARI Health | San Diego, CA

DPV Assay of Racemic Methadol in Variable Biomatrices

Cybin IRL Limited | CRO: Worldwide Clinical Trials | Dublin, Ireland

A Phase III, Placebo-Controlled, Randomized, Double-Blind Trial of Oral Doses of CYB003 to Assess Combined Safety and Efficacy in Humans with Major Depressive Disorder (APPROACH)

Cybin IRL Limited | CRO: Worldwide Clinical Trials | Dublin, Ireland

A Phase III Long-Term Extension Trial with Optional Additional Doses of CYB003 to Assess the Safety and Long-Term Efficacy in Participants with Major Depressive Disorder (EXTEND)

Paul Daley, PhD | Alexander Shulgin Research Institute, Inc. (ASRI) | Berkeley, CA

Synthesis, Analysis and Structure-Activity Relationships of Hallucinogenic Drugs Acting on Biogenic Amine Systems

Definium Therapeutics (previously Mind Medicine, Inc.) | New York, NY

A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled, 12-Week Study (Part A) with a 40-Week Open-label Extension (Part B) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Generalized Anxiety (PANORAMA)

Definium Therapeutics (previously Mind Medicine, Inc.) | New York, NY

A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, 12-week Study (Part A) with a 40-week Open-label Extension (Part b) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Major Depressive Disorder – Emerge (EMERGE)

Definium Therapeutics (previously Mind Medicine, Inc.) | New York, NY

A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, 12-Week Study (Part A) with a 40-Week Open-Label Extension (Part B) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Generalized Anxiety (VOYAGE)

Charles Grob, MD | Lundquist Institute for Biomedical Innovation | Torrance, CA

Pragmatic Trial of Psilocybin Therapy in Palliative Care (PT2PC): A Multicenter Triple-blind Phase 2 Randomized Controlled Trial of Psilocybin Therapy for Demoralized Adults Near the End of Life (PT2PC)

Boris Dov Heifets, MD, PhD | Stanford University | Palo Alto, CA

Effects of Classical Hallucinogens on Learning and Memory

Brook Henry, PhD | University of California, San Diego | San Diego, CA

Cannabis Effects on Antiretroviral Therapy Pharmacokinetics and Neurotoxicity

Deron Herr, PhD | Sanford Benham Prebys Medical Discovery Institute | La Jolla, CA

Biosynthesis and Biological Mechanism of Minor Cannabinoids

Hound Labs, Inc | Fremont, CA

Study to Evaluate Performance of the Hound Cannabis Breathalyzer - On Demand

Yih-ing Hser, PhD | University of California, Los Angeles/NIDA | Los Angeles, CA

Randomized Controlled Pilot Trial of Extended-Buprenorphine vs. Sublingual Buprenorphine-naloxone in Rural Settings (RXR)

Incannex Healthcare Pty Ltd | CRO: Fortrea | New South Wales, Australia

RePOSA-Revealing the Efficacy of IHL-42X Use in Patients with OSA: A Phase II/III, Randomised, Double-Blind Clinical Trial to Determine the Safety and Efficacy of IHL-42X in Subjects with Obstructive Sleep Apnoea Who Are Intolerant, Non-Compliant, or Naïve to Positive Airway Pressure (RePOSA)

Stephen V. Mahler, PhD | University of California, Irvine | Irvine, CA

Therapeutic Effects of Psychedelic Drugs in Rats

Stephen Marder, MD | Veterans Administration | Los Angeles, CA

A Randomized, Double-Blind, Single-Site Phase II 2-Arm Study to Compare the Safety and Preliminary Efficacy of Manualized MDMA-Assisted Therapy to Low Dose D-Amphetamine Assisted Therapy in Veterans for the Treatment of Moderate to Severe PTSD (IVAPT3)

Medical University of South Carolina | Charleston, SC

Life's end Benefits of cannabidiol and tetrahydrocannabinol (LiBBY)

Leslie Morland, PsyD | Veterans Administration San Diego Healthcare System | San Diego, CA

MDMA-Assisted Massed Prolonged Exposure for PTSD (IVAPT4)

Leslie Morland, PsyD | Veterans Administration San Diego Healthcare System | San Diego, CA

MDMA-Assisted Brief Cognitive Behavioral Conjoint Therapy for PTSD (IVAPT2)

National Institute on Drug Abuse/ Veterans Administration (NIDA/VA) | Bethesda, MD

Randomized, Placebo-Controlled, Multi-Site Trial of Extended-Release Naltrexone Injection/Bupropion XL Tablets in the Treatment of Methamphetamine Use Disorder (NIDA-VACSP,)

Marissa Raymond-Flesch, MD, MPH | University of California, San Francisco | San Francisco, CA

Study of Psilocybin for the Treatment of Anorexia Nervosa in Young Adults (SPANYA)

Carolyn Rodriguez, MD, PhD | Stanford University | Stanford, CA

A Randomized, Two-Arm, Double-Blind, Phase II Study to Investigate the Safety and Preliminary Efficacy of MDMA-Assisted Cognitive Behavioral Therapy (CBT) Compared with Methamphetamine (MA)-Assisted Cognitive Behavioral Therapy in Participants at Least 18 Years Old with Obsessive-Compulsive Disorder

Patricia Suppes, MD, PhD | VA Palo Alto Healthcare System | Palo Alto, CA

A Randomized Trial to Compare MDMA-Assisted Therapy (MDMA-AT) versus Cognitive Processing Therapy (CPT), a VA Standard of care for PTSD, for the Treatment of Severe Post-Traumatic Stress Disorder (IVAPT1)

University of Pittsburgh | Pittsburgh, PA

Prehospital Analgesia Intervention trial (PAIN)

University of Texas Southwestern | CRO: The Emmes Company | Rockville, MD

Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2) (NIDA CTN-0109)

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

The Cellular Basis of Motivated Behaviors in Health and Disease: Assessment of Acute and Persistent Changes in Behavioral and Neural Correlates of Emotional Valence Processing Produced by Psilocybin

U.S. Department of Veterans Affairs | West Haven, CT

Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

Usona Institute | CRO: Worldwide Clinical Trials Limited | Madison, WI

A Phase 3, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Psilocybin in Adults with Major Depressive Disorder (PSIL301)

Cory Weissman, MD, PhD | UC San Diego Department of Psychiatry | La Jolla, CA

Psilocybin-Assisted Therapy for Physician Well-Being and Burnout: Feasibility, Safety, Clinical Effectiveness and Biomarkers of Response [PAT-B (Psilocybin-Assisted Therapy for Physician Well-Being and Burnout)], (PAT-B)

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

A Double-Blinded, Active Placebo-Controlled, Randomized Trial Examining the Feasibility and Preliminary Efficacy of Psilocybin Therapy for People with Chronic Low Back Pain

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease: A Pilot Study

Yale University/ National Institute on Drug Abuse (NIDA) | New Haven, CT

Office-Based Methadone Versus Buprenorphine to Address Retention in Medication for Opioid Use Disorder Treatment - A Randomized Pragmatic Hybrid Effectiveness/Implementation Trial (NIDA CTN-0131)

TABLE 3

RESEARCH STUDIES CLOSED IN 2025

Beckley Psytech Ltd. | Worldwide Clinical Trials Limited | Nottingham, UK

A Quadruple Masked, Dose-Finding Study to Evaluate the Efficacy and Safety of Intranasal BPL-003 in Patients with Treatment-Resistant Depression. (CORE Study)

Ellen Breen, PhD | University of California, San Diego | La Jolla, CA

In Defense Against Vaping Nicotine and Cannabis - Alarmins

Nancy Buckley, PhD | California State Polytechnic University | Pomona, CA

Investigating the Effect of Delta-9-tetrahydrocannabinol (THC) on the Susceptibility to Systemic C. Albicans Infection in Mice Treated with an Anti-Cancer Drug

Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Morrisville, NC

A Phase II, Multicentre, Randomised, Double-Blind, Controlled Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of COMP360 in Participants with Recurrent Major Depressive Disorder (COMP 104)

Nissar Darmani, PhD | Western University Health Sciences, | Pomona, CA

Project 1: Mechanisms of Vomiting Induced by Chemotherapeutics, Related Emetics, and GI disorders.

Davide Dulcis, PhD | University of California, San Diego | La Jolla, CA

Effects of Neonatal Nicotine Exposure on Dopamine Neurons

Randall Espinoza, MD, MPH | University of California, Los Angeles | Los Angeles, CA

Psilocybin Pilot for Treatment-Resistant Depression (TRD)

Olivier George, PhD | University of California, San Diego | La Jolla, CA

Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments

Olivier George, PhD | University of California, San Diego | La Jolla, CA

Animal Models of Addiction: Preliminary Studies of Vaporized THC Self-Administration in a Rat Model

Incannex Healthcare Pty Ltd | CRO: Fortrea | New South Wales, Australia

RePOSA-Revealing the Efficacy of IHL-42X Use in Patients with OSA: A Phase II/III, Randomised, Double-Blind Clinical Trial to Determine the Safety and Efficacy of IHL-42X in Subjects with Obstructive Sleep Apnoea Who Are Intolerant, Non-Compliant, or Naïv (RePOSA)

Peter Leeming, PhD | S&B Pharma LLC (dba Norac Pharma) | Azusa, CA

Panel Approved Research Project

Stephen Mahler, PhD | University of California, Irvine | Irvine, CA

Neural Circuits Underlying Motivation and Addiction

Robert Malenka, MD, PhD | Stanford University | Palo Alto, CA

The Role of Oxytocin in the Pathogenesis of Autism

Jacobo Mintzer, MD | Medical University of South Carolina | Charleston, SC

Life's end Benefits of cannaBidiol and tetrahydrocannabinol (LiBBY)

David Olson, PhD | University of California, Davis | Davis, CA

Chemical Modulation of Neural Plasticity, Learning and Memory

Dilworth Parkinson, PhD | Lawrence Berkeley National Lab | Emeryville, CA

X-ray Microtomography of Pharmaceuticals at the Advanced Light Source for Avadel

Anca M. Pasca, MD | Stanford University | Palo Alto, CA

Exploring the Potential Role of Psychedelics in the Treatment of the Psychiatric Sequelae of 22q11.2 Deletion Syndrome

Jeanne Paz, PhD | University of California, San Francisco | San Francisco, CA

Role of Cannabidiol (CBD) in Inflammation in Genetic and Acquired Epilepsy

Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA

Antinociceptive Effects of Cannabinoids in Rodent Models: Cannabinoids in a Mouse Model of Sickle Cell Disease

Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA

1. Effect of Adolescent Cannabis Exposure in Adult Mice and Rats
2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

Matthew Springer, PhD | University of California, San Francisco | San Francisco, CA

Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers

Francesca Telese, PhD | University of California, San Diego | La Jolla, CA

Epigenetic Regulation of Gene Expression in the Brain

Transcend Therapeutics | New York, NY

An Evaluation of the Safety and Efficacy of Methylone for the Treatment of PTSD IMPACT-2 (Investigation of Methylone for Post-Traumatic Stress Disorder [PTSD]) (IMPACT-2)

Vertex Pharmaceuticals, Inc. | Boston, MA

A Phase 2, Randomized, Double-blind, Placebo-controlled, Dose-ranging Study Evaluating the Efficacy and Safety of VX-993 for Acute Pain After a Bunionectomy

Xinmin Simon Xie, PhD | AfaSci Research Laboratories | Redwood City, CA

Study Pharmacological Effects of Psychedelic Tryptamines, DMT, 5-OH-DMT and 5-MeO-DMT on Electrocutaneous Stimulation-Induced Migraine and Trigeminal Pain Model in Rodents

APPENDIX A
OPEN (THROUGH DECEMBER 31, 2025)
SCHEDULE I AND SCHEDULE II
ACADEMIC AND INDEPENDENT HUMAN RESEARCH STUDIES

Catherine Ayers, PhD and Brian Martis MD | VA San Diego Healthcare System | San Diego, CA
Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

Ausaf Bari, MD, PhD | University of California, Los Angeles | Los Angeles, CA
Electrophysiological Correlates of Opioid Use and its Associated Changes in Affect Using Direct Invasive Human Neuronal Recordings

Anya Bershada, MD, PhD | University of California, Los Angeles | Los Angeles, CA
Tolerability of MDMA in Schizophrenia

Baruch Rael Cahn, MD, PhD | University of Southern California (USC) | Los Angeles, CA
An Exploratory Study of Feasibility, Efficacy, and Mechanisms of Mindfulness-Assisted Psychedelic Therapy

Bayliss J. Camp, PhD | California Department of Motor Vehicles | Sacramento, CA
Cannabis Consumption and Driving Impairment Assessment on a Closed Course

Robin Carhart-Harris, PhD | University of California, San Francisco | San Francisco, CA
2 x 2 Factorial, Double-Blind, Randomized Study of ‘Set and Setting’: A Translational Study in Healthy Volunteers (Set and Setting [S&S])

Robin Carhart-Harris, PhD | University of California, San Francisco | San Francisco, CA
Multivariate Neural and Physiological Correlates of Psychedelic Sub-States: A Within-Subjects, Healthy Volunteer Study with Experience-Sampling (Insight-2)

Alexander Chen, MD | University of Southern California | Los Angeles, CA
Use of Single-Dose Pre-operative Oral Methadone for Pain Management in Outpatient Arthroscopic Hip and Knee Procedures

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

High Potency Cannabis: Acute and Protracted Effects

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Effects of Smoked Cannabis on Pain and Opioid Withdrawal among People on Long-term Opioid Treatment (CANLOT)

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Sex- and Age-Dependent Effects of Smoked and Oral Delta-9-THC

Ziva Cooper, PhD | University of California, Los Angeles/CHP | Los Angeles, CA

Evaluation of Oral THC and CBD in Oral Fluid, Pharmacokinetics, and Subjective and Neurocognitive Effects in Men and Women

Ziva Cooper, PhD | University of California, Los Angeles/ CHP | Los Angeles, CA

Evaluation of Smoked THC and CBD in Oral fluid, Pharmacokinetics, and Subjective and Neurocognitive Effects in Men and Women (S-TACOFs)

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Analgesic, Appetite-Stimulating, and Subjective Effects of Cannabigerol Administered Alone and in Combination with Delta-9-tetrahydrocannabinol (ASCENT)

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Subjective and Analgesic Effects of Terpene, Beta-Caryophyllene and Myrcene, Vaporized Alone and in Combination with THC

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Interactions Between Delta-9-THC and CBD: A Controlled Human Drug Administration Study Probing a Harm Reduction Strategy

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences Between Men and Women

Timothy Furnish, MD | University of California, San Diego | San Diego, CA

Behavioral and Neural Mechanisms Supporting Psilocybin Assisted Therapy for Phantom Limb Pain

Alison Giovanelli, PhD | University of California, San Francisco | San Francisco, CA

Impacts of THC Potency of Cannabis Concentrates and THC Metabolism on Cognitive Impairment in Young Adults

Brook Henry, PhD | University of California, San Diego | San Diego, CA

Cannabis Effects on Antiretroviral Therapy Pharmacokinetics and Neurotoxicity

David Hessel, PhD | University of California, Davis | Sacramento, CA

Randomized Controlled Trial of Quillivant in Intellectual Disability with ADHD

Richard T. Lee, MD | City of Hope National Medical Center | Irvine, CA

A Pilot Study to Evaluate the Benefits of Phytocannabinoids for the Treatment of Chronic Chemotherapy-Induced Peripheral Neuropathy

Stephen Marder, MD | VA Greater Los Angeles Healthcare System | Los Angeles, CA

A Randomized, Double-Blind, Single-Site Phase II 2-Arm Study to Compare the Safety and Preliminary Efficacy of Manualized MDMA-Assisted Therapy to Low Dose D-Amphetamine Assisted Therapy in Veterans for the Treatment of Moderate to Severe PTSD (IVAPT3)

Leslie Morland, PsyD | Veterans Administration San Diego Healthcare System | San Diego, CA

MDMA-Assisted Massed Prolonged Exposure for PTSD (IVAPT4)

Leslie Morland, PsyD | Veterans Administration San Diego Healthcare System | San Diego, CA

MDMA-Assisted Brief Cognitive Behavioral Conjoint Therapy for PTSD (IVAPT2)

Jeremy Pettus, MD | University of California, San Diego | La Jolla, CA

The Effects of THC on Glucose Metabolism and Endothelial Function in Subjects with Type 2 Diabetes

Marissa Raymond-Flesch, MD, M.P.H. | University of California, San Francisco | San Francisco, CA

Study of Psilocybin for the Treatment of Anorexia Nervosa in Young Adults (SPANYA)

Shannon Remick, MD | Veterans Administration, Loma Linda | Loma Linda, CA

Open-Label Phase 2 Study of MDMA-Assisted Psychotherapy in Veterans with Combat-Related, Refractory PTSD

Carolyn Rodriguez, MD, PhD | Stanford University | Stanford, CA

A Randomized, Two-Arm, Double-Blind, Phase II Study to Investigate the Safety and Preliminary Efficacy of MDMA-Assisted Cognitive Behavioral Therapy (CBT) Compared with Methamphetamine (MA)-Assisted Cognitive Behavioral Therapy in Participants at Least 18 Years Old with Obsessive-Compulsive Disorder

Michael Silver, PhD | University of California, Berkeley | Berkeley, CA

Investigating the Persisting Effects of a Single Dose of Psilocybin on Cognition, Predictive Coding, and Affect in Healthy Older Adults

Michael A. Silver, PhD | University of California, Berkeley | Berkeley, CA

Investigating the Mechanisms of the Effects of Psilocybin on Visual Perception and Visual Representations in the Brain

Gideon St. Helen, PhD | University of California, San Francisco | San Francisco, CA

Understanding the Clinical Pharmacology of Marijuana-Tobacco Co-Administration (CANNIC Study)

Patricia Suppes, MD, PhD | VA Palo Alto Healthcare System | Palo Alto, CA

A Randomized Trial to Compare MDMA-Assisted Therapy (MDMA-AT) versus Cognitive Processing Therapy (CPT), a VA Standard of care for PTSD, for the Treatment of Severe Post-Traumatic Stress Disorder (IVAPT1)

Patricia Suppes, MD, PhD | VA Palo Alto Healthcare System | Palo Alto, CA

The Safety and Efficacy of Psilocybin in Participants with Severe Treatment-Resistant Depression (P-TRD)

Marc Weintraub, PhD | University of California, Los Angeles | Los Angeles, CA

Psilocybin - Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

Cory Weissman, MD, PhD | University of California, San Diego | La Jolla, CA

Psilocybin-Assisted Therapy for Physician Well-Being and Burnout: Feasibility, Safety, Clinical Effectiveness and Biomarkers of Response [PAT-B (Psilocybin-Assisted Therapy for Physician Well-Being and Burnout)], (PAT-B)

Marc Weitraub, PhD | University of California, Los Angeles | Los Angeles, CA

Group Psilocybin-Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

Scott A. Wilke, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Psychostimulant Augmentation of Repetitive TMS (rTMS) for the Treatment of Major Depressive Disorder: A Randomized, Placebo-Controlled Clinical Trial

Leanne Williams, PhD | Stanford university | Palo Alto, CA

Randomized, Double-Blind, Placebo-Controlled, Within-Subject Study on the Influence of MDMA on Risk and Reward Circuits of the Brain

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

Comparison of the Effects of PEX20 (Oral Psilocin), PEX30 (Sublingual Psilocin), and PEX10 (Oral Psilocybin) in Healthy Adults

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

A Double-Blinded, Active Placebo-Controlled, Randomized Trial Examining the Feasibility and Preliminary Efficacy of Psilocybin Therapy for People with Chronic Low Back Pain

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

An Open-Label Pilot Study Examining the Feasibility, Safety, and Effectiveness of Psilocybin Therapy for Depression in Bipolar II Disorder

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease: A Pilot Study

Joshua Woolley, MD, PhD / Prasad Shirvalkar, MD, PhD | University of California, San Francisco | San Francisco, CA

PINS: Psilocybin with Intracranial Neural Sensing (PINS)

Fadel Zeidan, PhD | University of California, San Diego | La Jolla, CA

Brain Mechanisms of Cannabis-Based Analgesia

APPENDIX B
OPEN (THROUGH DECEMBER 31, 2025)
SCHEDULE I AND SCHEDULE II
CLINICAL DRUG TRIAL RESEARCH STUDIES

Atai Therapeutics, Inc. | CRO: Worldwide Clinical Trials | New York, NY

A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial to Assess the Efficacy, Safety, and Tolerability of Repeated Doses of VLS-01 Buccal Film in Participants with Treatment Resistant Depression

Columbia University | New York, NY

Efficacy of Intravenous Sub-Dissociative Ketamine Versus Intravenous Morphine in Children with Acute Pain (MoKA)

Compass Pathfinder Limited | CRO: ICON plc | Cheshire, UK

A Phase III, Multicentre, Randomised, Double-Blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants with Treatment-Resistant Depression

Compass Pathfinder Limited | CRO: ICON plc | Cheshire, UK

A Phase III, Multi-Centre, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy, Safety, and Tolerability of a Single Administration of COMP360 in Participants with Treatment-Resistant Depression (COMP 005)

Cybin IRL Limited | CRO: Worldwide Clinical Trials | Dublin, Ireland

A Phase III, Placebo-Controlled, Randomized, Double-Blind Trial of Oral Doses of CYB003 to Assess Combined Safety and Efficacy in Humans with Major Depressive Disorder (APPROACH)

Cybin IRL Limited | Worldwide Clinical Trials | Dublin, Ireland

An Efficacy and Safety, Phase III, Multi-center, Double-Blind, Randomized Controlled Study Comparing 2 Active Doses of CYB003 and Placebo in Eligible Participants with Major Depressive Disorder (EMBRACE)

Cybin IRL Limited | CRO: Worldwide Clinical Trials | Dublin, Ireland

A Phase III Long-Term Extension Trial with Optional Additional Doses of CYB003 to Assess the Safety and Long-Term Efficacy in Participants with Major Depressive Disorder (EXTEND)

Definium Therapeutics (previously Mind Medicine, Inc.) | New York, NY

A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled, 12-Week Study (Part A) with a 40-Week Open-label Extension (Part B) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Generalized Anxiety Disorder – Panorama. (PANORAMA)

Definium Therapeutics (previously Mind Medicine, Inc.) | New York, NY

A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled, 12-Week Study (Part A) with a 40-Week Open-label Extension (Part B) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Generalized Anxiety Disorder – Voyage (VOYAGE)

Definium Therapeutics (previously Mind Medicine, Inc.) | New York, NY

A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, 12-week Study (Part A) with a 40-week Open-label Extension (Part b) Evaluating the Efficacy and Safety of Oral MM120 Compared to Placebo in the Treatment of Adults with Major Depressive Disorder – Emerge (EMERGE)

Hound Labs, Inc | Fremont, CA

Study to Evaluate Performance of the Hound Cannabis Breathalyzer - On Demand

Charles Grob, MD | Lundquist Institute for Biomedical Innovation | Torrance, CA

Pragmatic Trial of Psilocybin Therapy in Palliative Care (PT2PC): A Multicenter Triple-blind Phase 2 Randomized Controlled Trial of Psilocybin Therapy for Demoralized Adults Near the End of Life (PT2PC)

Transcend Therapeutics | New York, NY

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of TSND-201 for the Treatment of PTSD

University of Pittsburgh | Pittsburgh, PA

Prehospital Analgesia Intervention trial (PAIN)

U.S. Department of Veterans Affairs | West Haven, CT

Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

Usona Institute | CRO: Worldwide Clinical Trials Limited | Madison, WI

A Phase 3, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Psilocybin in Adults with Major Depressive Disorder

APPENDIX C

OPEN (THROUGH DECEMBER 31, 2025) CONTROLLED SUBSTANCE USE DISORDER TREATMENT RESEARCH STUDIES

University of Cincinnati | Cincinnati, OH

Evaluation of Tirzepatide as an Adjunct to Buprenorphine for the Treatment of Opioid Use Disorder: A Pragmatic, Multisite, Double-Blind, Randomized, Placebo-Controlled, Trial. (TAB Trial, NIDA CTN-0152)

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Safety Profile of 25 mg Psilocybin in Individuals with Cocaine Use Disorder

Ethan Cowan, MD, MS | Icahn School of Medicine at Mount Sinai | New York, NY

Safety and Efficacy of High Dose BUP Induction in Fentanyl Positive Emergency Department Patients (UG3)

Yale University/ National Institute on Drug Abuse (NIDA) | New Haven, CT

ED-Initiated Standard Versus High Dose Buprenorphine Induction (ED-ENVISION) (CTN-0145)

Yale University/ National Institute on Drug Abuse (NIDA) | New Haven, CT

Office-Based Methadone Versus Buprenorphine to Address Retention in Medication for Opioid Use Disorder Treatment - A Randomized Pragmatic Hybrid Effectiveness/Implementation Trial (NIDA CTN-0131)

Yih-ing Hser, PhD | University of California, Los Angeles/NIDA | Los Angeles, CA

Randomized Controlled Pilot Trial of Extended-Buprenorphine vs. Sublingual Buprenorphine-naloxone in Rural Settings (RXR) (CTN-0102-XR)

NIH/National Institute on Drug Abuse | CRO: The Emmes Company | Rockville, MD

Optimizing Retention, Duration and Discontinuation Strategies for Opioid Use Disorder Pharmacotherapy (RDD) (CTN-01001)

Clear Scientific | CRO: Parexel International | Cambridge, MA

A Single-Dose Study to Evaluate Safety and Efficacy of CS-1103 in Participants Receiving a Single Dose of Methamphetamine

National Institute on Drug Abuse/ Veterans Administration (NIDA/VA) | Bethesda, MD

Randomized, Placebo-Controlled, Multi-Site Trial of Extended-Release Naltrexone Injection/Bupropion XL Tablets in the Treatment of Methamphetamine Use Disorder (NIDA-VACSP)

University of Texas Southwestern | CRO: The Emmes Company | Rockville, MD

Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2) (NIDA CTN-0109)

Nicky Mehtani, MD, MPH | University of California, San Francisco | San Francisco, CA

Pilot Trial of Ketamine Assisted Psychotherapy for Methamphetamine Use Disorder and HIV Risk Reduction

NIDA CCTN Clinical Coordinating Center | CRO: Emmes Corp | Rockville, MD

Emergency Department-Initiated Buprenorphine Validation Trial ((ED-INNOVATION) (CTN-0099)

Braeburn, Inc. | CRO: Lotus Clinical Research | Plymouth Meeting, PA

A Phase I, Open-Label Study to Demonstrate Bioequivalence Between Two Different Manufacturers of CAM2038 (Weekly) and CAM 2038 (Monthly) 128mg in Adult Patients with Opioid Use Disorder

APPENDIX D

OPEN (THROUGH DECEMBER 31, 2025) SCHEDULE I NON-HUMAN RESEARCH STUDIES

Hillel Adesnik, PhD | University of California, Berkeley | Berkeley, CA

Cellular and Circuit Mechanisms of Sensory Perception

Stephan Anagnostaras, PhD | University of California, San Diego | La Jolla, CA

Effects of Psychedelic Treatment on Mouse Models of Social Behavior, Addiction, Depression, Fear Memory, and Anxiety

Roberto C. Andresen Eguiluz, PhD | University of California, Merced | Merced, CA

Establishing the Role of Cannabinoids in Altering the Function of the Cardiovasculature

Marc Azar, PhD | Behavioral Pharma, Inc. | La Jolla, CA

Synergistic Effects of Psilocin and/or Psilocybin and COMPOUND TSO on Depressive Activity Using the Mouse Forced Swim Test

Melissa Bauman, PhD | University of California, Davis | Sacramento, CA

Neurodevelopmental Impact of Prenatal Cannabis Exposure

Ryan Baxter, PhD | University of California, Merced | Merced, CA

Light Control and Oxidation Potential of Cannabinoids

Kevin Beier, PhD | University of California, Irvine | Irvine, CA

Reversing Maladaptive Plasticity Using Psilocybin

Kevin Beier, PhD | University of California, Irvine | Irvine, CA

Effect of Adolescent THC Exposure on Future Substance Abuse

Joseph Califano, MD | University of California, San Diego | La Jolla, CA

THC-Cannabinoid Receptor Pathway and CBD Activation of GPCRs on Cannabinoid Signaling Pathways in Head and Neck Squamous Cell Carcinoma (HNSCC)

Cesear Corona, PhD | Promega Corporation/ Usona Institute | San Luis Obispo, CA

Development of Tools and Technologies Toward Understanding the Mechanism of Action, Safety, and Therapeutic Potential of Psychedelic Compounds.

Natasha Courchesne-Krak, PhD | CARI Health | San Diego, CA

DPV Assay of Racemic Methadol in Variable Biomatrices

Cesear Corona, PhD | Promega Corporation/ Usona Institute | San Luis Obispo, CA

Synthesis and Biological Evaluation of Psychedelic Tryptamine Natural Products: Psilocybin, Psilocin, 5-MeO-DMT and N,N-DMT

Paul Daley, PhD | Alexander Shulgin Research Institute, Inc. (ASRI) | Berkeley, CA

Synthesis, Analysis and Structure-Activity Relationships of Hallucinogenic Drugs Acting on Biogenic Amine Systems

Karl Deisseroth, MD, PhD | Stanford University | Stanford, CA

The Effect of DMT and 5-MeO DMT on Brainwide Activity and Behavior

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA

Effects of LSD on Brain-Wide Neural Activity and Behavior

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA

Neural Circuit Dynamics of LSD-Induced Psychosis

Hugo Destailats, PhD | Lawrence Berkeley National Laboratory | Berkeley, CA

Assessment of Secondhand and Thirdhand Exposures to Cannabis-Related Indoor Contaminants

Nicholas DiPatrizio, PhD | University of California, Riverside | Riverside, CA

Mechanism of Endocannabinoid Control of Feeding and Energy Balance

Gul Dolen, MD, PhD | UC Berkeley | Berkeley, CA

Molecular, Synaptic and Circuit Mechanisms Underlying Social Cognition and Reward in Health and Disease

Maxellende Ezin, PhD | Loyola Marymount University | Los Angeles, CA

Effects of Psilocybin on Embryonic Development

Jerel Fields, PhD | University of California, San Diego | La Jolla, CA

Cannabis and Pathogenic Mechanisms Influencing Blood Brain Barrier Function in HIV

Christie Fowler, PhD | University of California, Irvine | Irvine, CA

Mechanisms of Drug Reinforcement

Neil Garg, PhD | University of California, Los Angeles | Los Angeles, CA

Optical and Electrochemical Detection of Tetrahydrocannabinol (THC) Towards a Functional Quantitative Breathalyzer

Andrea Gomez, PhD | University of California, Berkeley | Berkeley, CA

The Molecular and Cellular Basis of Psychedelic-Induced Synaptic Plasticity and Cognitive Flexibility

Xiaomin Cathy Gong, PhD | Diazyme Laboratories, Inc. | Poway, CA

γ -Hydroxybutyric Acid (GHB) Assay or γ -Hydroxybutyrate (GHB) Assay

Adam Halberstadt, PhD | University of California, San Diego | La Jolla, CA

The Next Generation of Hallucinogens: A New Class of Synthetic Psychoactive Drugs

Christopher Hamad, MD | University of California, Los Angeles | Los Angeles, CA

The Impact of Cannabis Exposure on Fracture Healing and Antimicrobial Immune Function in a Murine Model

Boris Dov Heifets, MD, PhD | Stanford University | Palo Alto, CA

Effects of Classical Hallucinogens on Learning and Memory

Judith Hellman, MD | University of California, San Francisco | San Francisco, CA

Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury

Deron Herr, PhD | Sanford Benham Prebys Medical Discovery Institute | La Jolla, CA

Biosynthesis and Biological Mechanism of Minor Cannabinoids

Jaime Inman, PhD | Lawrence Berkeley National Laboratory | Berkeley, CA

Contribution of Genetic Factors to Individual Differences in Anxiety in Response to the Cannabinoids THC and CBD

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA

Vaccine Research (Vaccines and Antidotes Against Drugs of Abuse)

Daniela Kaufer, PhD | University of California, Berkeley | Berkeley, CA

Unraveling Biological Mechanisms of Psychedelic Medicine Using Preclinical Models of PTSD

Mazen Kheirbek, PhD | University of California, San Francisco | San Francisco, CA

Testing Psilocybin as a Therapeutic in Mouse Models of Anxiety and Depression-Related Behavior

Frank Kochinke, PhD | LC Pharmaceuticals, LLC | San Diego, CA

Sustained Delivery of Psilocybin, Psilocin, DMT, LSD, MDMA, THC, and 5-MEO-DMT, with Synthesis of API's

David E. Krantz, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Serotonergic Signaling in Drosophila

Alexander Kuttyrev, PhD | Aurora Fine Chemicals, LLC | San Diego, CA

Water Soluble Cannabinoids, Preparation and Use

Stephan Lammel, PhD | University of California, Berkeley | Berkeley, CA

Organization and Function of Neural Circuits in the Mammalian Brain

Peter Leeming, PhD | S & B Pharma LLC, dba Norac Pharma | Azusa, CA

Research on the Synthesis of Delta-9- Tetrahydrocannabinol

Byungkook Lim, PhD | University of California, San Diego | La Jolla, CA

Studying the Impact of Psychedelic Drugs on the Neural Circuit and Behavioral Effects of Drugs of Abuse and Social Anxiety.

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Molecular and Circuit Effects of Psychedelic Drugs on the Central Nervous System

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Discovery and Reconstruction of Mescaline Biosynthesis

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Development of Fluorescent Sensors for Psychedelic Drugs

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Multi-omic Characterization of the Effects of Psychedelic Drugs on the CNS

Loren Looger, PhD | University of California, San Diego | La Jolla, CA

Investigating the Neuroimmunomodulatory Properties of Psilocybin.

Pamela A. Maher, PhD | Salk Institute | La Jolla, CA

Therapeutic Relevance of Cannabinoids for Alzheimer's Disease

Stephen V. Mahler, PhD | University of California, Irvine | Irvine, CA

Therapeutic Effects of Psychedelic Drugs in Rats

Stephen Mahler, PhD | University of California, Irvine | Irvine, CA

Neural Circuits Underlying Heroin Motivation and Addiction

Uri Manor, PhD | University of California, San Diego | La Jolla, CA

Therapeutic Potential and Mechanism of Psychoplastogen Compounds

M. Cecilia Marcondes, PhD | San Diego Biomedical Research Institute | San Diego, CA

Molecular Effects of Cannabinoids on the Blood Brain Barrier in HIV-infected Brain

Lisa A. Miller, PhD | University of California, Davis | Davis, CA

Novel Use of Human iPSC Derived Airway Progenitor Cells to Measure E-Cigarette Toxicity

Bradley S. Moore, PhD | University of California, San Diego | La Jolla, CA

Biosynthesis and Biological Mechanism of Minor Cannabinoids

Christopher Moxham, PhD | Rarebase | Palo Alto, CA

Profiling the Transcriptomic Response of Select Controlled Substances in Vitro

Alysson Muotri, PhD | University of California, San Diego | La Jolla, CA

Mechanisms of Action of Psychedelics in Human Brain Organoids

Alysson Muotri, PhD | University of California, San Diego | La Jolla, CA

The Impact of CBD/THC on Human Neurodevelopment

Jonathan Nassi, PhD | Inscopix | CRO: LifeSource Biomedical Services LLC | Moffett Field, CA

Investigation of the Impact of Psychedelic Compounds on Prefrontal Cortical Circuits

David Olson, PhD | University of California, Davis | Davis, CA

Chemical Modulation of Neural Plasticity, Learning and Memory (2)

Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA

A Translational Study on the Short- and Long-term Effects of High Dose Delta-9-tetrahydrocannabinol (THC)

Susan Powell, PhD | Veterans Affairs San Diego Healthcare System | San Diego, CA

Preclinical Neuropsychopharmacology of Psychoactive Substances

Jeffrey Sall, PhD, MD | University of California, San Francisco | San Francisco, CA

Effect of Cannabinoid Exposure on Brain Development and Behavior in a Postnatal Rat Model

Ranmal Samarasinghe, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Exploring the Differential Brain Network Electrodynamics and Cellular Impacts of Psilocybin and MDMA Versus SSRIs Using Human Brain Organoids

Suzaynn Schick, PhD | University of California, San Francisco | San Francisco, CA

Measuring Environmental Tobacco and Cannabis: Pollutants and Exposures

Mehrdad Shamloo, PhD | Stanford University | Palo Alto, CA

Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases

Gaia Skibinski, PhD | Herophilus, Inc. | San Francisco, CA

Pharmacological Effects of Controlled Substances in Cerebral Organoids

Vikaas Sohal, MD, PhD | University of California, San Francisco | San Francisco, CA

Investigating Brain Circuits that Underlie Potentially Therapeutic Psychedelic Drugs

Mark Sussman, PhD | San Diego State University | San Diego, CA

Adolescent Vaping Accelerates Cardiac Aging

Mark Sussman, PhD | San Diego State University | San Diego, CA

Prenatal Nicotine Tetrahydrocannabinol Exposure Promotes Myocardial Damage: A Brain-Heart Parallel

Michael Taffe, PhD | University of California, San Diego | La Jolla, CA

Panel Approved Research Project (1)

Michael Taffe, PhD | University of California, San Diego | La Jolla, CA

Panel Approved Research Project (2)

Yi Tang, PhD | University of California, Los Angeles | Los Angeles, CA

Synthetic Biology Approaches to Cannabinoid Diversification and Production

Francesca Telese, MD | University of California, San Diego | La Jolla, CA

Neurobiological Mechanisms of Reward Behavior

Doris Tsao, PhD | University of California, Berkeley | Berkeley, CA

Panel Approved Research Project

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

Assessment of Changes in Behavioral and Neural Correlates of Social and Physical Pain Processing Produced By Tetrahydrocannabinol (THC)

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

The Cellular Basis of Motivated Behaviors in Health and Disease: Assessment of Acute and Persistent Changes in Behavioral and Neural Correlates of Emotional Valence Processing Produced by Psilocybin

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

Assessment of changes in behavioral and neural correlates of social processing produced by 3,4-methylenedioxymethamphetamine (MDMA)

Kay Tye, PhD | Salk Institute for Biological Studies | La Jolla, CA

Assessment of Changes in Behavioral and Neural Correlates of Self- Versus Other- Processing Produced By N,N-dimethyltryptamine (DMT)

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA

Laboratory Scale Biosynthesis of DMT and Related Substituted Tryptamine Compounds in Baker's Yeast

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA

Laboratory Scale Biosynthesis of Psilocybin in Baker's Yeast

Aaron Vollrath, PhD | Lin-Zhi International, Inc. | Santa Clara, CA

Cross-Reactivity Characterization of LSD, LSD Metabolites, and Lysergamide Analogs for Homogeneous Immunoassay Development

Aaron Vollrath, PhD | Lin-Zhi International, Inc. | Santa Clara, CA

Lin-Zhi Nitazene Immunoassay Development Study

Charles Wang, MD, PhD, MPH | Loma Linda University | Loma Linda, CA

Investigating Effects and Underlying Epigenomic Mechanisms Following Prenatal THC Exposure

Audrey Williams, PhD | Lawrence Livermore National Laboratory | Livermore, CA

Illicit Cannabis Cultivation in California: Illegal Pesticides and Risks to Human Health (IMPACT-2)

Joseph Wu, MD, PhD | Stanford University | Stanford, CA

Human iPSCs for Elucidating Cardiovascular Risks of Cannabis

Li Ye, PhD | The Scripps Research Institute | La Jolla, CA

A Novel Strategy Toward Spatially Resolved Pharmacology

Moonbin Yim, PhD | ARK Diagnostics, Inc. | Fremont, CA

Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing: Cross-Reactivity Evaluation Plan and Protocol Fentanyl Analogs and Cannabimimetics

Anjie Zhen, PhD | University of California, Los Angeles | Los Angeles, CA

Define the Effects and Mechanism of THC and CBD On IFN-I Mediated Inflammation and Immune Dysfunction During HIV Infection

Natalie Zlebnik, PhD | University of California, Riverside | Riverside, CA

Therapeutic Potential of Cannabinoids for Cocaine Relapse

Yi Zuo, PhD | University of California, Santa Cruz | Santa Cruz, CA

Chemical Modulation of Neural Circuits and Plasticity

APPENDIX E

STATUTORY AUTHORITY CONCERNING THE RESEARCH ADVISORY PANEL (2025)

(Statutory changes approved in [2025 \(AB 1103\)](#) became effective on January 1, 2026 and will appear in the 2026 Annual Report that is published in 2027.)

Health and Safety Code Section 11213 - Persons and Research Using Controlled Substances

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and Section 11481. Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Health and Safety Code Section 11392 - Authorized Acquisition for Use in Bona Fide Research, Instruction or Analysis

Spores or mycelium capable of producing mushrooms or other material which contains psilocin or psilocybin may be lawfully obtained and used for bona fide research, instruction, or analysis, if not in violation of federal law, and if the research, instruction, or analysis is approved by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Health and Safety Code Section 11478 - Use of Cannabis in Research Projects

Cannabis may be provided by the Attorney General to the heads of research projects which have been registered by the Attorney General, and which have been approved by the research advisory panel pursuant to Section 11480. The head of the approved research project shall personally receipt for such quantities of cannabis and shall make a record of their disposition. The receipt and record shall be retained by the Attorney General. The head of the approved research project shall also, at intervals and in the manner required by the research advisory panel, report the progress or conclusions of the research project

Health and Safety Code Section 11480 - Research Advisory Panel

- (a) The Legislature finds that there is a need to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects.
- (b) There is a Research Advisory Panel that consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, the State Public Health Officers, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a

(Section 11480 Cont.)

physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this state who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the panel. Members of the panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

- (c) The Research Advisory Panel shall appoint two special members to the Research Advisory Panel, who shall serve at the pleasure of the Research Advisory Panel only during the period Article 6 (commencing with Section 11260) of Chapter 5 remains effective. The additional members shall be physicians and surgeons, and who are board certified in oncology, ophthalmology, or psychiatry.
- (d) The panel shall annually select a chairperson from among its members.
- (e) The panel may hold hearings on, and in other ways study, research projects concerning cannabis or hallucinogenic drugs in this state. Members of the panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.
- (f) The panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of cannabis or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of cannabis pursuant to Section 11478.
- (g) The panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of cannabis to the Attorney General.
- (h) The panel shall report annually to the Legislature and the Governor those research projects approved by the panel, the nature of each research project, and, where available, the conclusions of the research project.

Health and Safety Code Section 11481 - Research Advisory Panel

The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the

(Section 11481 Cont.)

chief of such approval. The panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The panel shall, annually and in the manner determined by the panel, report to the Legislature and the Governor those research projects approved by the panel, the nature of each research project, and where available, the conclusions of the research project.

Health and Safety Code Section 11603 - Attorney General

The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

Health and Safety Code Section 11604 - Attorney General

The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

Health and Safety Code Section 11362.9 - Cannabis Research Program

- (a) (1) It is the intent of the Legislature that the state commission objective scientific research by the premier research institute of the world, the University of California, regarding the efficacy and safety of administering cannabis, its naturally occurring constituents, and synthetic compounds, as part of medical treatment. If the Regents of the University of California, by appropriate resolution, accept this responsibility, the University of California shall create a program, to be known as the California Cannabis Research Program, hosted by the Center for Medicinal Cannabis Research. Whenever “California Marijuana Research Program” appears in any statute, regulation, or contract, or in any other code, it shall be construed to refer to the California Cannabis Research Program.
 - (2) The program shall develop and conduct studies intended to ascertain the general medical safety and efficacy of cannabis and, if found valuable, shall develop medical guidelines for the appropriate administration and use of cannabis. The studies may examine the effect of cannabis on motor skills, the health and safety effects of cannabis, cannabinoids, and other related constituents, and other behavioral and health outcome
- (b) The program may immediately solicit proposals for research projects to be included in the cannabis studies. Program requirements to be used when evaluating responses to its solicitation for proposals shall include, but not be limited to, all of the following:

(Section 11362.9 Cont.)

- (1) Proposals shall demonstrate the use of key personnel, including clinicians or scientists and support personnel, who are prepared to develop a program of research regarding the general medical efficacy and safety of cannabis.
 - (2) Proposals shall contain procedures for outreach to patients with various medical conditions who may be suitable participants in research on cannabis.
 - (3) Proposals shall contain provisions for a patient registry.
 - (4) Proposals shall contain provisions for an information system that is designed to record information about possible study participants, investigators, and clinicians, and deposit and analyze data that accrues as part of clinical trials.
 - (5) Proposals shall contain protocols suitable for research on cannabis, addressing patients diagnosed with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV), cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The proposal may also include research on other serious illnesses, provided that resources are available, and medical information justifies the research.
 - (6) Proposals shall demonstrate the use of a specimen laboratory capable of housing plasma, urine, and other specimens necessary to study the concentration of cannabinoids in various tissues, as well as housing specimens for studies of toxic effects of cannabis.
 - (7) Proposals shall demonstrate the use of a laboratory capable of analyzing cannabis, provided to the program under this section, for purity and cannabinoid content and the capacity to detect contaminants.
- (c) In order to ensure objectivity in evaluating proposals, the program shall use a peer review process that is modeled on the process used by the National Institutes of Health, and that guards against funding research that is biased in favor of or against particular outcomes. Peer reviewers shall be selected for their expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the applicants or the topic of an approach taken in the proposed research. Peer reviewers shall judge research proposals on several criteria, foremost among which shall be both of the following:
- (1) The scientific merit of the research plan, including whether the research design and experimental procedures are potentially biased for or against a particular outcome.
 - (2) Researchers' expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the topic of, and the approach taken in, the proposed research.

(Section 11362.9 Cont.)

- (d) If the program is administered by the Regents of the University of California, any grant research proposals approved by the program shall also require review and approval by the research advisory panel.
- (e) It is the intent of the Legislature that the program be established as follows:
 - (1) The program shall be located at one or more University of California campuses that have a core of faculty experienced in organizing multidisciplinary scientific endeavors and, in particular, strong experience in clinical trials involving psychopharmacologic agents. The campuses at which research under the auspices of the program is to take place shall accommodate the administrative offices, including the director of the program, as well as a data management unit, and facilities for detection and analysis of various naturally occurring and synthetic cannabinoids, as well as storage of specimens.
 - (2) When awarding grants under this section, the program shall utilize principles and parameters of the other well-tested statewide research programs administered by the University of California, modeled after programs administered by the National Institutes of Health, including peer review evaluation of the scientific merit of applications.
 - (3) The scientific and clinical operations of the program shall occur partly at University of California campuses and partly at other postsecondary institutions that have clinicians or scientists with expertise to conduct the required studies. Criteria for selection of research locations shall include the elements listed in subdivision (b) and, additionally, shall give particular weight to the organizational plan, leadership qualities of the program director, and plans to involve investigators and patient populations from multiple sites.
 - (4) The funds received by the program shall be allocated to various research studies in accordance with a scientific plan developed by the Scientific Advisory Council. As the first wave of studies is completed, it is anticipated that the program will receive requests for funding of additional studies. These requests shall be reviewed by the Scientific Advisory Council.
 - (5) The size, scope, and number of studies funded shall be commensurate with the amount of appropriated and available program funding.
- (f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.
- (g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, cannabis. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

(Section 11362.9 Cont.)

- (h) The program shall make every effort to recruit qualified patients and qualified physicians from throughout the state.
- (i) The cannabis studies shall employ state-of-the-art research methodologies.
- (j) The program shall ensure that all cannabis used in the studies is of the appropriate medicinal quality. Cannabis used by the program may be obtained from the National Institute on Drug Abuse or any other entity authorized by the appropriate federal agencies, the Attorney General pursuant to Section 11478, or may be cultivated by the program pursuant to applicable federal and state laws and regulations.
- (k) The program may review, approve, or incorporate studies and research by independent groups presenting scientifically valid protocols for medical research, regardless of whether the areas of study are being researched by the committee.
- (l)
 - (1) To enhance understanding of the efficacy and adverse effects of cannabis as a pharmacological agent, the program shall conduct focused controlled clinical trials on the usefulness of cannabis in patients diagnosed with AIDS or HIV, cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The program may add research on other serious illnesses, provided that resources are available and medical information justifies the research. The studies shall focus on comparisons of both the efficacy and safety of methods of administering the drug to patients, including inhalational, tinctural, and oral, evaluate possible uses of cannabis as a primary or adjunctive treatment, and develop further information on optimal dosage, timing, mode of administration, and variations in the effects of different cannabinoids and varieties of cannabis or synthetic compounds that simulate the effects of naturally occurring cannabinoids. The studies may also focus on examining testing methods for detecting harmful contaminants in cannabis, including, but not limited to, mold, bacteria, and mycotoxins that could cause harm to patients.
 - (2) The program shall examine the safety of cannabis in patients with various medical disorders, including the interaction of cannabis with other drugs, relative safety of inhalation versus oral forms, and the effects on mental function in medically ill persons.
 - (3) The program shall be limited to providing for objective scientific research to ascertain the efficacy and safety of cannabis as part of medical treatment, and should not be construed as encouraging or sanctioning the social or recreational use of cannabis.
- (m)
 - (1) Subject to paragraph (2), the program shall, prior to approving proposals, seek to obtain research protocol guidelines from the National Institutes of Health and shall, if the National Institutes of Health issues research protocol guidelines, comply with those guidelines.
 - (2) If, after a reasonable period of time of not less than six months and not more than a year has elapsed from the date the program seeks to obtain guidelines

(Section 11362.9 Cont.)

pursuant to paragraph (1), no guidelines have been approved, the program may proceed using the research protocol guidelines it develops.

- (n) In order to maximize the scope and size of the cannabis studies, the program may do any of the following:
- (1) Solicit, apply for, and accept funds from foundations, private individuals, and all other funding sources that can be used to expand the scope or timeframe of the cannabis studies that are authorized under this section. The program shall not expend more than 5 percent of its General Fund allocation in efforts to obtain money from outside sources.
 - (2) Include within the scope of the cannabis studies other cannabis research projects that are independently funded and that meet the requirements set forth in subdivisions (a) to (c), inclusive. In no case shall the program accept funds that are offered with any conditions other than that the funds be used to study the efficacy and safety of cannabis as part of medical treatment.
- (o) (1) Within six months of the effective date of this section, the program shall report to the Legislature, the Governor, and the Attorney General on the progress of the cannabis studies.
- (2) Thereafter, the program shall issue a report to the Legislature every 24 months detailing the progress of the studies. The interim reports required under this paragraph shall include, but not be limited to, data on all of the following:
- (A) The names and number of diseases or conditions under study.
 - (B) The number of patients enrolled in each study, by disease.
 - (C) Any scientifically valid preliminary findings.
- (p) If the Regents of the University of California implement this section, the President of the University of California, or the president's designee, shall appoint a multidisciplinary Scientific Advisory Council, not to exceed 15 members, to provide policy guidance in the creation and implementation of the program. Members shall be chosen on the basis of scientific expertise. Members of the council shall serve on a voluntary basis, with reimbursement for expenses incurred in the course of their participation. The members shall be reimbursed for travel and other necessary expenses incurred in their performance of the duties of the council.
- (q) No more than 10 percent of the total funds appropriated may be used for all aspects of the administration of this section.
- (r) This section shall be implemented only to the extent that funding for its purposes is appropriated by the Legislature.

(Section 11362.9 Cont.)

- (s) Money appropriated to the program pursuant to subdivision (e) of Section 34019 of the Revenue and Taxation Code shall only be used as authorized by the Control, Regulate and Tax Adult Use of Marijuana Act (AUMA).
- (t) This section does not limit or preclude cannabis-related research activities at any campus of the University of California.

Health and Safety Code Section 11839.3 - Duties of Department of Health Care Services

(a) In addition to the duties authorized by other statutes, the department shall perform all of the following:

- (1) License the establishment of narcotic treatment programs in this state to use narcotic replacement therapy in the treatment of addicted persons whose addiction was acquired or supported by the use of a narcotic drug or drugs, not in compliance with a physician and surgeon's legal prescription, except that the Research Advisory Panel shall have authority to approve methadone or LAAM research programs. The department shall establish and enforce the criteria for the eligibility of patients to be included in the programs, program operation guidelines, such as dosage levels, recordkeeping and reporting, urinalysis requirements, take-home doses of controlled substances authorized for use pursuant to Section 11839.2, security against redistribution of the narcotic replacement drugs, and any other regulations that are necessary to protect the safety and well-being of the patient, the local community, and the public, and to carry out this chapter. A program may admit a patient to narcotic maintenance or narcotic detoxification treatment at the discretion of the medical director. The program shall assign a unique identifier to, and maintain an individual record for, each patient of the program. The arrest and conviction records and the records of pending charges against a person seeking admission to a narcotic treatment program shall be furnished to narcotic treatment program directors upon written request of the narcotic treatment program director provided the request is accompanied by a signed release from the person whose records are being requested.
- (2) Inspect narcotic treatment programs in this state and ensure that programs are operating in accordance with the law and regulations. The department shall have sole responsibility for compliance inspections of all programs in each county. Annual compliance inspections shall consist of an evaluation by onsite review of the operations and records of licensed narcotic treatment programs' compliance with applicable state and federal laws and regulations and the evaluation of input from local law enforcement and local governments, regarding concerns about the narcotic treatment program. At the conclusion of each inspection visit, the department shall conduct an exit conference to explain the cited deficiencies to the program staff and to provide recommendations to ensure compliance with applicable laws and regulations. The department shall provide an inspection report to the licensee within 30 days of the completed onsite review describing the program deficiencies.

A corrective action plan shall be required from the program within 30 days of receipt of the inspection report. All corrective actions contained in the plan shall be

(Section 11839.3 Cont.)

implemented within 30 days of receipt of approval by the department of the corrective action plan submitted by the narcotic treatment program. For programs found not to be in compliance, a subsequent inspection of the program shall be conducted within 30 days after the receipt of the corrective action plan in order to ensure that corrective action has been implemented satisfactorily. Subsequent inspections of the program shall be conducted to determine and ensure that the corrective action has been implemented satisfactorily. For purposes of this requirement, “compliance” shall mean to have not committed any of the grounds for suspension or revocation of a license provided for under subdivision (a) of Section 11839.9 or paragraph (2) of subdivision (b) of Section 11839.9. Inspection of narcotic treatment programs shall be based on objective criteria including, but not limited to, an evaluation of the programs’ adherence to all applicable laws and regulations and input from local law enforcement and local governments. Nothing in this section shall preclude counties from monitoring their contract providers for compliance with contract requirements.

- (3) Charge and collect licensure fees. In calculating the licensure fees, the department shall include staff salaries and benefits, related travel costs, and state operational and administrative costs. Fees shall be used to offset licensure and inspection costs, not to exceed actual costs.
 - (4) Study and evaluate, on an ongoing basis, narcotic treatment programs including, but not limited to, the adherence of the programs, to all applicable laws and regulations and the impact of the programs on the communities in which they are located.
 - (5) Provide advice, consultation, and technical assistance to narcotic treatment programs to ensure that the programs comply with all applicable laws and regulations and to minimize any negative impact that the programs may have on the communities in which they are located.
 - (6) In its discretion, to approve local agencies or bodies to assist it in carrying out this chapter provided that the department may not delegate responsibility for inspection or any other licensure activity without prior and specific statutory approval. However, the department shall evaluate recommendations made by county alcohol and drug program administrators regarding licensing activity in their respective counties.
 - (7) The director may grant exceptions to the regulations adopted under this chapter if he or she determines that this action would improve treatment services or achieve greater protection to the health and safety of patients, the local community, or the general public. An exception shall not be granted if it is contrary to, or less stringent than, the federal laws and regulations that govern narcotic treatment programs.
- (b) It is the intent of the Legislature in enacting this section, in order to protect the general public and local communities, that take-home doses of narcotic replacement therapy medications authorized for use pursuant to Section 11839.2 shall only be provided when

(Section 11839.3 Cont.)

the patient is clearly adhering to the requirements of the program, and if daily attendance at a clinic would be incompatible with gainful employment, education, responsible homemaking, retirement or medical disability, or if the program is closed on Sundays or holidays and providing a take-home dose is not contrary to federal laws and regulations governing narcotic treatment programs. The department shall define “satisfactory adherence” and shall ensure that patients not satisfactorily adhering to their programs shall not be provided take-home doses. A narcotic treatment program medical director shall determine whether or not to dilute take-home doses.

- (c) There is established in the State Treasury the Narcotic Treatment Program Licensing Trust Fund. All licensure fees collected from the providers of narcotic treatment services shall be deposited in this fund. Except as otherwise provided in this section, if funds remain in this fund after appropriation by the Legislature and allocation for the costs associated with narcotic treatment licensure actions and inspection of narcotic treatment programs, a percentage of the excess funds shall be annually rebated to the licensees based on the percentage their licensing fee is of the total amount of fees collected by the department. A reserve equal to 10 percent of the total licensure fees collected during the preceding fiscal year may be held in each trust account to reimburse the department if the actual cost for the licensure and inspection exceeds fees collected during a fiscal year.
- (d) Notwithstanding any provision of this code or regulations to the contrary, the department shall have sole responsibility and authority for determining if a state narcotic treatment program license shall be granted and for administratively establishing the maximum treatment capacity of a license. However, the department shall not increase the capacity of a program unless it determines that the licensee is operating in full compliance with applicable laws and regulations.

Health and Safety Code Section 11839.7 - License Required; Fee; Compliance with Laws and Regulations; Disclosure of Fee Increases

- (a) (1) Each narcotic treatment program authorized to use narcotic replacement therapy in this state, except narcotic treatment research programs approved by the Research Advisory Panel, shall be licensed by the department.
- (2) Each narcotic treatment program, other than a program owned and operated by the state, county, city, or city and county, shall, upon application for licensure and for renewal of a license, pay an annual license fee to the department. July 1 shall be the annual license renewal date.
- (3) The department shall set the licensing fee at a level sufficient to cover all departmental costs associated with licensing incurred by the department, but the fee shall not, except as specified in this section, increase at a rate greater than the Consumer Price Index. The fees shall include the department’s share of pro rata charges for the expenses of state government. The fee may be paid quarterly in arrears as determined by the department. Fees paid quarterly in arrears shall be due and payable on the last day of each quarter except for the

(Section 11839.7 Cont.)

fourth quarter for which payment shall be due and payable no later than May 31. A failure of a program to pay renewal license fees by the due date shall give rise to a civil penalty of one hundred dollars (\$100) a day for each day after the due date. Second and subsequent inspection visits to narcotic treatment programs that are operating in noncompliance with the applicable laws and regulations shall be charged a rate of one-half the program's annual license fee or one thousand dollars (\$1,000), whichever is less, for each visit.

- (4) Licensing shall be contingent upon determination by the department that the program is in compliance with applicable laws and regulations and upon payment of the licensing fee. A license shall not be transferable.
- (5) (A) As used in this chapter, "quarter" means July, August, and September; October, November, and December; January, February, and March; and April, May, and June.
- (B) As used in this chapter, "license" means a basic permit to operate a narcotic treatment program. The license shall be issued exclusively by the department and operated in accordance with a patient capacity that shall be specified, approved, and monitored solely by the department.
- (b) Each narcotic treatment program, other than a program owned and operated by the state, county, city, or city and county, shall be charged an application fee that shall be at a level sufficient to cover all departmental costs incurred by the department in processing either an application for a new program license, or an application for an existing program that has moved to a new location.
- (c) Any licensee that increases fees to the patient, in response to increases in licensure fees required by the department, shall first provide written disclosure to the patient of that amount of the patient fee increase that is attributable to the increase in the licensure fee. This provision shall not be construed to limit patient fee increases imposed by the licensee upon any other basis.

Health and Safety Code Section 24172 - Experimental Subject's Bill of Rights; Contents

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent.

Except as otherwise provided in Section 24175, this list shall include, but not be limited to the subject's right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(Section 24172 Cont.)

- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
- (i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Health and Safety Code Section 24173 - Informed Consent

As used in this chapter, "informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

- (a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
- (b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
- (c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(Section 24173 Cont.)

- (1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.
 - (2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
 - (3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
 - (4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
 - (5) An estimate of the expected recovery time of the subject after the experiment. The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.
 - (6) An offer to answer any inquiries concerning the experiment or the procedures involved.
 - (7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.
 - (8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.
 - (9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.
 - (10) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment.
 - (11) For purposes of this section, “material” means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.
- (d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

Health and Safety Code Section 11480.5 - Research Advisory Panel as Multimember Advisory Body; Report to Legislature on Backlog of Applications

- (a) The Research Advisory Panel shall be considered a multimember advisory body solely for the purposes of Section 11123.5 of the Government Code.
- (b) The panel shall provide a report to the Legislature on or before January 1, 2026, that provides an update on the backlog of applications that includes, at minimum, the number of backlog applications that have been reviewed and how many are still pending review.
- (c) This section shall remain in effect only until January 1, 2027, and as of that date is repealed.

California Government Code Section 11126 - Closed Sessions

- (a) (1) This article shall not be construed to prevent a state body from holding closed sessions during a regular or special meeting to consider the appointment, employment, evaluation of performance, or dismissal of a public employee or to hear complaints or charges brought against that employee by another person or employee unless the employee requests a public hearing.
- (2) As a condition to holding a closed session on the complaints or charges to consider disciplinary action or to consider dismissal, the employee shall be given written notice of their right to have a public hearing, rather than a closed session, and that notice shall be delivered to the employee personally or by mail at least 24 hours before the time for holding a regular or special meeting. If notice is not given, any disciplinary or other action taken against any employee at the closed session shall be null and void.
- (3) The state body also may exclude from any public or closed session, during the examination of a witness, any or all other witnesses in the matter being investigated by the state body.
- (4) Following the public hearing or closed session, the body may deliberate on the decision to be reached in a closed session.
- (b) For the purposes of this section, “employee” does not include any person who is elected to, or appointed to a public office by, any state body. However, officers of the California State University who receive compensation for their services, other than per diem and ordinary and necessary expenses, shall, when engaged in that capacity, be considered employees. Furthermore, for purposes of this section, the term employee includes a person exempt from civil service pursuant to subdivision (e) of Section 4 of Article VII of the California Constitution.
- (c) This article shall not be construed to do any of the following:
 - (1) Prevent state bodies that administer the licensing of persons engaging in businesses or professions from holding closed sessions to prepare, approve, grade, or administer examinations.

(Section 11126 Cont.)

- (2) Prevent an advisory body of a state body that administers the licensing of persons engaged in businesses or professions from conducting a closed session to discuss matters that the advisory body has found would constitute an unwarranted invasion of the privacy of an individual licensee or applicant if discussed in an open meeting, provided the advisory body does not include a quorum of the members of the state body it advises. Those matters may include review of an applicant's qualifications for licensure and an inquiry specifically related to the state body's enforcement program concerning an individual licensee or applicant where the inquiry occurs prior to the filing of a civil, criminal, or administrative disciplinary action against the licensee or applicant by the state body.
- (3) Prohibit a state body from holding a closed session to deliberate on a decision to be reached in a proceeding required to be conducted pursuant to Chapter 5 (commencing with Section 11500) or similar provisions of law.
- (4) Grant a right to enter any correctional institution or the grounds of a correctional institution where that right is not otherwise granted by law, nor shall anything in this article be construed to prevent a state body from holding a closed session when considering and acting upon the determination of a term, parole, or release of any individual or other disposition of an individual case, or if public disclosure of the subjects under discussion or consideration is expressly prohibited by statute.
- (5) Prevent any closed session to consider the conferring of honorary degrees, or gifts, donations, and bequests that the donor or proposed donor has requested in writing to be kept confidential.
- (6) Prevent the Alcoholic Beverage Control Appeals Board or the Cannabis Control Appeals Panel from holding a closed session for the purpose of holding a deliberative conference as provided in Section 11125.
- (7) (A) Prevent a state body from holding closed sessions with its negotiator prior to the purchase, sale, exchange, or lease of real property by or for the state body to give instructions to its negotiator regarding the price and terms of payment for the purchase, sale, exchange, or lease.
 - (B) However, prior to the closed session, the state body shall hold an open and public session in which it identifies the real property or real properties that the negotiations may concern and the person or persons with whom its negotiator may negotiate.
 - (C) For purposes of this paragraph, the negotiator may be a member of the state body.
 - (D) For purposes of this paragraph, "lease" includes renewal or renegotiation of a lease.
 - (E) This paragraph shall not preclude a state body from holding a closed session for discussions regarding eminent domain proceedings pursuant to subdivision (e).

(Section 11126 Cont.)

- (8) Prevent the California Postsecondary Education Commission from holding closed sessions to consider matters pertaining to the appointment or termination of the Director of the California Postsecondary Education Commission.
- (9) Prevent the Council for Private Postsecondary and Vocational Education from holding closed sessions to consider matters pertaining to the appointment or termination of the Executive Director of the Council for Private Postsecondary and Vocational Education.
- (10) Prevent the Franchise Tax Board from holding closed sessions for the purpose of discussion of confidential tax returns or information the public disclosure of which is prohibited by law, or from considering matters pertaining to the appointment or removal of the Executive Officer of the Franchise Tax Board.
- (11) Require the Franchise Tax Board to notice or disclose any confidential tax information considered in closed sessions, or documents executed in connection therewith, the public disclosure of which is prohibited pursuant to Article 2 (commencing with Section 19542) of Chapter 7 of Part 10.2 of Division 2 of the Revenue and Taxation Code.
- (12) Prevent the Board of State and Community Corrections from holding closed sessions when considering reports of crime conditions under Section 6027 of the Penal Code.
- (13) Prevent the State Air Resources Board from holding closed sessions when considering the proprietary specifications and performance data of manufacturers.
- (14) Prevent the State Board of Education or the Superintendent of Public Instruction, or any committee advising the board or the Superintendent, from holding closed sessions on those portions of its review of assessment instruments pursuant to Chapter 5 (commencing with Section 60600) of Part 33 of Division 4 of Title 2 of the Education Code during which actual test content is reviewed and discussed. The purpose of this provision is to maintain the confidentiality of the assessments under review.
- (15) Prevent the Department of Resources Recycling and Recovery or its auxiliary committees from holding closed sessions for the purpose of discussing confidential tax returns, discussing trade secrets or confidential or proprietary information in its possession, or discussing other data, the public disclosure of which is prohibited by law.
- (16) Prevent a state body that invests retirement, pension, or endowment funds from holding closed sessions when considering investment decisions. For purposes of consideration of shareholder voting on corporate stocks held by the state body, closed sessions for the purposes of voting may be held only with respect to election of corporate directors, election of independent auditors, and other financial issues that could have a material effect on the net income of the corporation. For the purpose of real property investment decisions that may be considered in a closed session pursuant to this paragraph, a state body shall also be exempt from the provisions of paragraph (7) relating to the identification of real properties prior to the closed session.

(Section 11126 Cont.)

- (17) Prevent a state body, or boards, commissions, administrative officers, or other representatives that may properly be designated by law or by a state body, from holding closed sessions with its representatives in discharging its responsibilities under Chapter 10 (commencing with Section 3500), Chapter 10.3 (commencing with Section 3512), Chapter 10.5 (commencing with Section 3525), or Chapter 10.7 (commencing with Section 3540) of Division 4 of Title 1 as the sessions relate to salaries, salary schedules, or compensation paid in the form of fringe benefits. For the purposes enumerated in the preceding sentence, a state body may also meet with a state conciliator who has intervened in the proceedings.
- (18) (A) Prevent a state body from holding closed sessions to consider matters posing a threat or potential threat of criminal or terrorist activity against the personnel, property, buildings, facilities, or equipment, including electronic data, owned, leased, or controlled by the state body, where disclosure of these considerations could compromise or impede the safety or security of the personnel, property, buildings, facilities, or equipment, including electronic data, owned, leased, or controlled by the state body.
- (B) Notwithstanding any other law, a state body, at any regular or special meeting, may meet in a closed session pursuant to subparagraph (A) upon a two-thirds vote of the members present at the meeting.
- (C) After meeting in closed session pursuant to subparagraph (A), the state body shall reconvene in open session prior to adjournment and report that a closed session was held pursuant to subparagraph (A), the general nature of the matters considered, and whether any action was taken in closed session.
- (D) After meeting in closed session pursuant to subparagraph (A), the state body shall submit to the Legislative Analyst written notification stating that it held this closed session, the general reason or reasons for the closed session, the general nature of the matters considered, and whether any action was taken in closed session. The Legislative Analyst shall retain for no less than four years any written notification received from a state body pursuant to this subparagraph.
- (19) Prevent the California Sex Offender Management Board from holding a closed session for the purpose of discussing matters pertaining to the application of a sex offender treatment provider for certification pursuant to Sections 290.09 and 9003 of the Penal Code. Those matters may include review of an applicant's qualifications for certification.
- (20) (A) Prevent the Research Advisory Panel established in Sections 11480 and 11481 of the Health and Safety Code from holding closed sessions for the purpose of discussing, reviewing, and approving research projects, including applications and amendment applications, that contain sensitive and confidential information, including, but not limited to, trade secrets, intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law.

(Section 11126 Cont.)

(B) This paragraph shall become inoperative on January 1, 2027.

(d) (1) Notwithstanding any other law, any meeting of the Public Utilities Commission at which the rates of entities under the commission's jurisdiction are changed shall be open and public.

(2) This article shall not be construed to prevent the Public Utilities Commission from holding closed sessions to deliberate on the institution of proceedings, or disciplinary actions against any person or entity under the jurisdiction of the commission.

(e) (1) This article shall not be construed to prevent a state body, based on the advice of its legal counsel, from holding a closed session to confer with, or receive advice from, its legal counsel regarding pending litigation when discussion in open session concerning those matters would prejudice the position of the state body in the litigation.

(2) For purposes of this article, all expressions of the lawyer-client privilege other than those provided in this subdivision are hereby abrogated. This subdivision is the exclusive expression of the lawyer-client privilege for purposes of conducting closed session meetings pursuant to this article. For purposes of this subdivision, litigation shall be considered pending when any of the following circumstances exist:

(A) An adjudicatory proceeding before a court, an administrative body exercising its adjudicatory authority, a hearing officer, or an arbitrator, to which the state body is a party, has been initiated formally.

(B) (i) A point has been reached where, in the opinion of the state body on the advice of its legal counsel, based on existing facts and circumstances, there is a significant exposure to litigation against the state body.

(ii.) Based on existing facts and circumstances, the state body is meeting only decide whether a closed session is authorized pursuant to clause (i).

(C) Based on existing facts and circumstances, the state body has decided to initiate or is deciding whether to initiate litigation.

(3) The legal counsel of the state body shall prepare and submit to it a memorandum stating the specific reasons and legal authority for the closed session. If the closed session is pursuant to subparagraph (A) of paragraph (2), the memorandum shall include the title of the litigation. If the closed session is pursuant to subparagraph (B) or (C) of paragraph (2), the memorandum shall include the existing facts and circumstances on which it is based. The legal counsel shall submit the memorandum to the state body prior to the closed session, if feasible, and in any case no later than one week after the closed session. The memorandum shall be exempt from disclosure pursuant to Section 7927.205.

(Section 11126 Cont.)

- (4) For purposes of this subdivision, “litigation” includes any adjudicatory proceeding, including eminent domain, before a court, administrative body exercising its adjudicatory authority, hearing officer, or arbitrator.
 - (5) Disclosure of a memorandum required under this subdivision shall not be deemed as a waiver of the lawyer-client privilege, as provided for under Article 3 (commencing with Section 950) of Chapter 4 of Division 8 of the Evidence Code.
- (f) In addition to subdivisions (a), (b), and (c), this article shall not be construed to do any of the following:
- (1) Prevent a state body operating under a joint powers agreement for insurance pooling from holding a closed session to discuss a claim for the payment of tort liability or public liability losses incurred by the state body or any member agency under the joint powers agreement.
 - (2) Prevent the examining committee established by the State Board of Forestry and Fire Protection, pursuant to Section 763 of the Public Resources Code, from conducting a closed session to consider disciplinary action against an individual professional forester prior to the filing of an accusation against the forester pursuant to Section 11503.
 - (3) Prevent the enforcement advisory committee established by the California Board of Accountancy pursuant to Section 5020 of the Business and Professions Code from conducting a closed session to consider disciplinary action against an individual accountant prior to the filing of an accusation against the accountant pursuant to Section 11503. This article shall not be construed to prevent the qualifications examining committee established by the California Board of Accountancy pursuant to Section 5023 of the Business and Professions Code from conducting a closed hearing to interview an individual applicant or accountant regarding the applicant's qualifications.
 - (4) Prevent a state body, as defined in subdivision (b) of Section 11121, from conducting a closed session to consider any matter that properly could be considered in closed session by the state body whose authority it exercises.
 - (5) Prevent a state body, as defined in subdivision (d) of Section 11121, from conducting a closed session to consider any matter that properly could be considered in a closed session by the body defined as a state body pursuant to subdivision (a) or (b) of Section 11121.
 - (6) Prevent a state body, as defined in subdivision (c) of Section 11121, from conducting a closed session to consider any matter that properly could be considered in a closed session by the state body it advises.
 - (7) Prevent the State Board of Equalization from holding closed sessions for either of the following:

(Section 11126 Cont.)

- (A) When considering matters pertaining to the appointment or removal of the Executive Secretary of the State Board of Equalization.
- (B) For the purpose of hearing confidential taxpayer appeals or data, the public disclosure of which is prohibited by law.
- (8) Require the State Board of Equalization to disclose any action taken in closed session or documents executed in connection with that action, the public disclosure of which is prohibited by law pursuant to Sections 15619 and 15641 of this code and Sections 833, 7056, 8255, 9255, 11655, 30455, 32455, 38705, 38706, 43651, 45982, 46751, 50159, 55381, and 60609 of the Revenue and Taxation Code.
- (9) Prevent the California Earthquake Prediction Evaluation Council, or other body appointed to advise the Director of Emergency Services or the Governor concerning matters relating to volcanic or earthquake predictions, from holding closed sessions when considering the evaluation of possible predictions.
- (g) This article does not prevent either of the following:
 - (1) The Teachers' Retirement Board or the Board of Administration of the Public Employees' Retirement System from holding closed sessions when considering matters pertaining to the recruitment, appointment, employment, or removal of the chief executive officer or when considering matters pertaining to the recruitment or removal of the Chief Investment Officer of the State Teachers' Retirement System or the Public Employees' Retirement System.
 - (2) The Commission on Teacher Credentialing from holding closed sessions when considering matters relating to the recruitment, appointment, or removal of its executive director.
- (h) This article does not prevent the Board of Administration of the Public Employees' Retirement System from holding closed sessions when considering matters relating to the development of rates and competitive strategy for plans offered pursuant to Chapter 15 (commencing with Section 21660) of Part 3 of Division 5 of Title 2.
- (i) This article does not prevent the Managed Risk Medical Insurance Board from holding closed sessions when considering matters related to the development of rates and contracting strategy for entities contracting or seeking to contract with the board, entities with which the board is considering a contract, or entities with which the board is considering or enters into any other arrangement under which the board provides, receives, or arranges services or reimbursement, pursuant to Part 6.2 (commencing with Section 12693), former Part 6.3 (commencing with Section 12695), former Part 6.4 (commencing with Section 12699.50), former Part 6.5 (commencing with Section 12700), former Part 6.6 (commencing with Section 12739.5), or former Part 6.7 (commencing with Section 12739.70) of Division 2 of the Insurance Code.

(Section 11126 Cont.)

- (j) This article shall not be construed to prevent the board of the State Compensation Insurance Fund from holding closed sessions in the following:
- (1) When considering matters related to claims pursuant to Chapter 1 (commencing with Section 3200) of Part 1 of Division 4 of the Labor Code, to the extent that confidential medical information or other individually identifiable information would be disclosed.
 - (2) To the extent that matters related to audits and investigations that have not been completed would be disclosed.
 - (3) To the extent that an internal audit containing proprietary information would be disclosed.
 - (4) To the extent that the session would address the development of rates, contracting strategy, underwriting, or competitive strategy, pursuant to the powers granted to the board in Chapter 4 (commencing with Section 11770) of Part 3 of Division 2 of the Insurance Code, when discussion in open session concerning those matters would prejudice the position of the State Compensation Insurance Fund.
- (k) The State Compensation Insurance Fund shall comply with the procedures specified in Section 11125.4 of the Government Code with respect to any closed session or meeting authorized by subdivision (j), and in addition shall provide an opportunity for a member of the public to be heard on the issue of the appropriateness of closing the meeting or session

California Government Code, Article 9 Section 11123.5 - Meetings

- (a) For purposes of this section, the following definitions apply:
- (1) “Participate remotely” means participation in a meeting at a location other than the physical location designated in the agenda of the meeting.
 - (2) “Remote location” means a location other than the primary physical location designated in the agenda of a meeting.
 - (3) “Teleconference” has the same meaning as in Section 11123.
- (b) In addition to the authorization to hold a meeting by teleconference pursuant to subdivision (b) of Section 11123 or Section 11123.2, any state body that is an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body may hold an open meeting by teleconference as described in this section, provided the meeting complies with all of the section’s requirements and, except as set forth in this section, it also complies with all other applicable requirements of this article.
- (c) A member of a state body as described in subdivision (b) who participates in a teleconference meeting from a remote location subject to this section’s requirements shall be listed in the minutes of the meeting.

(Section 11123.5 Cont.)

- (d) The state body shall provide notice to the public at least 24 hours before the meeting that identifies any member who will participate remotely by posting the notice on its internet website and by emailing notice to any person who has requested notice of meetings of the state body under this article. The location of a member of a state body who will participate remotely is not required to be disclosed in the public notice or email and need not be accessible to the public. The notice of the meeting shall also identify the primary physical meeting location designated pursuant to subdivision (f).
- (e) This section does not affect the requirement prescribed by this article that the state body post an agenda of a meeting at least 10 days in advance of the meeting. The agenda shall include information regarding the physical meeting location designated pursuant to subdivision (f), but is not required to disclose information regarding any remote location.
- (f) A state body described in subdivision (b) shall designate the primary physical meeting location in the notice of the meeting where members of the public may physically attend the meeting, observe and hear the meeting, and participate. At least one staff member of the state body shall be present at the primary physical meeting location during the meeting. The state body shall post the agenda at the primary physical meeting location, but need not post the agenda at a remote location.
- (g) When a member of a state body described in subdivision (b) participates remotely in a meeting subject to this section's requirements, the state body shall provide a means by which the public may remotely hear audio of the meeting or remotely observe the meeting, including, if available, equal access equivalent to members of the state body participating remotely. The applicable teleconference phone number or internet website, or other information indicating how the public can access the meeting remotely, shall be in the 24-hour notice described in subdivision (b) that is available to the public.
- (h)
 - (1) Except as provided in paragraph (2), the members of the state body shall visibly appear on camera during the open portion of a meeting that is publicly accessible via the internet or other online platform.
 - (2) The visual appearance of a member of a state body on camera may cease only when the appearance would be technologically impracticable, including, but not limited to, when the member experiences a lack of reliable broadband or internet connectivity that would be remedied by joining without video, or when the visual display of meeting materials, information, or speakers on the internet or other online platform requires the visual appearance of a member of a state body on camera to cease.
 - (3) If a member of the body does not appear on camera due to challenges with internet connectivity, the member shall announce the reason for their nonappearance when they turn off their camera.
- (i) Upon discovering that a means of remote access required by subdivision (g) has failed during a meeting, the state body described in subdivision (b) shall end or adjourn the

(Section 11123.5 Cont.)

meeting in accordance with Section 11128.5. In addition to any other requirements that may apply, the state body shall provide notice of the meeting's end or adjournment on its internet website and by email to any person who has requested notice of meetings of the state body under this article. If the meeting will be adjourned and reconvened on the same day, further notice shall be provided by an automated message on a telephone line posted on the state body's agenda, or by a similar means, that will communicate when the state body intends to reconvene the meeting and how a member of the public may hear audio of the meeting or observe the meeting.

(j) This section does not limit or affect the ability of a state body to hold a teleconference meeting under another provision of this article.

(k) This section shall remain in effect only until January 1, 2026, and as of that date is repealed.

(Amended by Stats. 2023, Ch. 216, Sec. 2. (SB 544) Effective January 1, 2024. Repealed as of January 1, 2026, by its own provisions. See later version added by Sec. 3 of Stats. 2023, Ch. 216)

