2024

Research Advisory Panel of California

RAPC
RESEARCH ADVISORY PANEL OF CALIFORNIA

54th Annual Report to the Governor and Legislature of California

Research Advisory Panel of California
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RESEARCH ADVISORY PANEL OF CALIFORNIA

LEGISLATIVE MANDATE

California law, pursuant to Health and Safety Code Sections 11480 and 11481, 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 disorder 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 study. The RAPC 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.

RESEARCH ADVISORY PANEL OF CALIFORNIA

2024 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 California State Governor

Martine D'Agostino
Deputy Attorney General, State of California Office of the Attorney General, Oakland
Appointed by the California State Attorney General

Patrick R. Finley, PharmD, BCPP
Professor Emeritus, University of California, San Francisco (UCSF) School of Pharmacy
Appointed by the California State Board of Pharmacy
(Term ended on August 4, 2024)

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
(Term began on December 5, 2024)

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
(Term began on July 16, 2024)

Cyrus Rangan, MD, FAAP, FACMT
Toxicologist and Assistant Deputy Director, Center for Healthy Communities California Department of Public Health
Designee for Public Health Officer Tomás Aragón, MD, DrPH
(Term began on August 6, 2024)

RAPC Staff

Tanveer Khan, PharmD
Executive Officer
Appointed by the California State Attorney General

2024 SUMMARY OF ACTIVITIES

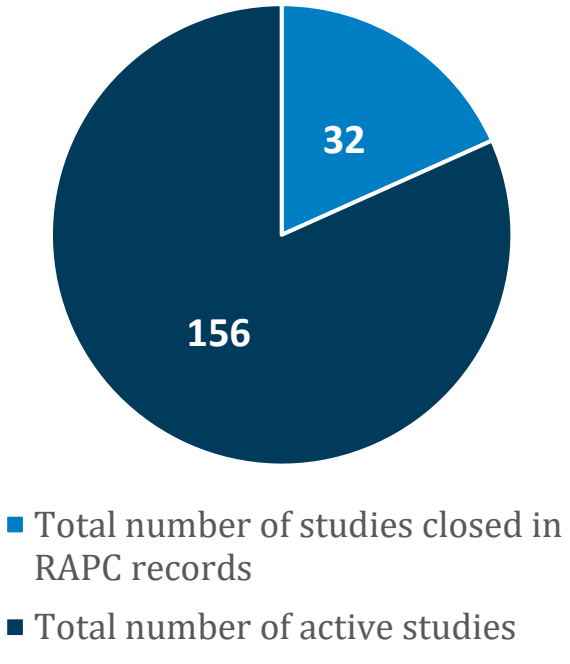
During 2024 (Jan. 1 – Dec. 31, 2024), the Research Advisory Panel of California (RAPC) approved a total of 54 new study applications and 50 amended applications from 29 studies. The 54 new study approvals included applications from 2023 and 2024. RAPC received 37 new study applications in 2024 and approved 30 of them. The remaining seven applications were either not approvable, withdrew their applications, or were exempt from RAPC review. Due to a procedural issue that affected RAPC in 2023 and 2024, the review and approval of an additional 24 new applications received in 2023 were also completed. That procedural issue was resolved with the approval of Assembly Bill 2841 on July 18, 2024.

The 54 new studies approved in 2024 were comprised of 38 human research studies and 16 non-human research studies. Fourteen human studies were clinical drug trials, 16 were academic or independent studies, and eight were substance use disorder treatment studies. Thirty-two studies were completed or terminated in 2024 and closed in RAPC records (see Figure 1).

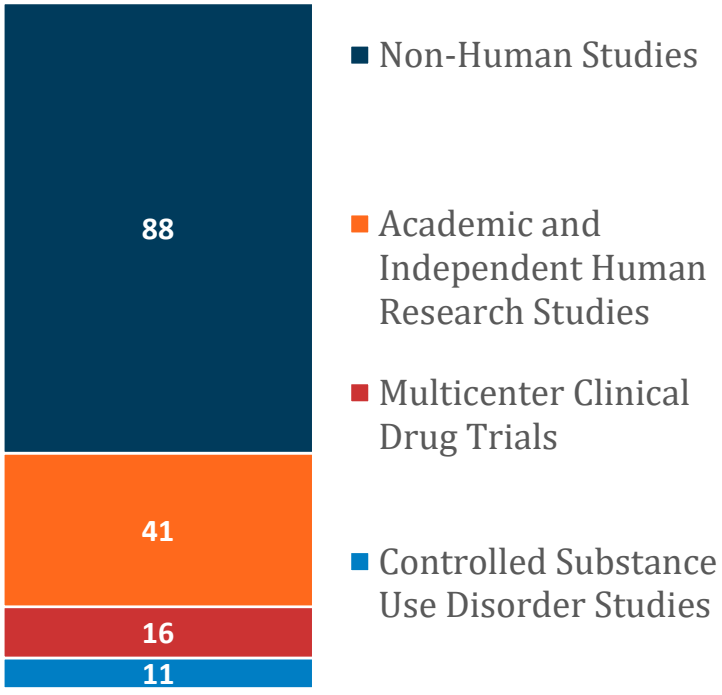
Table 1 in this report lists the new studies approved in 2024. Table 2 lists amended studies approved in 2024. Table 3 lists the studies completed or terminated in 2024 and closed in RAPC records. At the end of 2024, RAPC was monitoring 156 active studies (for a breakdown, see Figure 2). See Appendices A, B, C, and D for specific listings.

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 2024. RAPC approval may be withdrawn if study activities deviate substantively from the approved protocol or conditions of Panel approval are not met.

2024 ACTIVE AND CLOSED STUDIES (Fig. 1)



2024 ACTIVE STUDIES BY TYPE (Fig. 2)



SELECTED RESEARCH FINDINGS

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

Dr. Gideon St. Helen, PhD, and colleagues at the Tobacco Research Center at University of California, San Francisco are conducting human research entitled *"Understanding the Clinical Pharmacology of Marijuana-Tobacco Co-administration. (CANNIC Study)."* Dr. St. Helen provided the following summary of this research:

> Marijuana, a federal illegal drug, is used by millions of people across all age groups, race, and sex. Tobacco, which causes more disease and death than any other preventable cause, is used by even more people. Importantly, most marijuana users also use tobacco. This is concerning because evidence suggests that the health risk of combined marijuana-tobacco use (also known as co-use) is greater than that caused by use of marijuana by itself. Understanding what leads to or causes sustained co-use of these two substances and the health consequences of co-use is important to preserving public health.
>
> Studies have described intake of Delta-9-tetrahydrocannabinol (THC), the primary psychoactive chemical in marijuana, and its effects from various marijuana-only products, including smoked, vaporized, and oral forms, but studies assessing the combined effects of marijuana and tobacco are scarce. To the best of our knowledge, no study has examined effects of marijuana and tobacco co-administration by systematically changing the amount of both THC and nicotine delivered to users. This has been a barrier to understanding the relationship between marijuana-tobacco co-use and health outcomes.
>
> The central aim of the project is to describe the pharmacokinetics and pharmacodynamics of THC-nicotine co-administration. In this foundational study, we will use a loose-leaf vaporizer to deliver doses of both THC and nicotine from marijuana and tobacco, respectively. We hypothesize that marijuana-tobacco co-administration will lead to larger effects than when the substances are used by themselves, particularly at lower doses of THC and nicotine. This includes higher THC and nicotine intake and systemic exposure, and more than additive cardiovascular responses. We will test these hypotheses with the following aims:
>
> 1. Describe and compare THC and nicotine pharmacokinetics and acute physiologic effects, including, heart rate changes, catecholamine release, skin blood flow, and platelet aggregation from various combinations of marijuana and tobacco;
>
> 2. Describe and compare sensory and subjective effects such as high, liking, craving reduction, and psychological reward from administration of various combinations of marijuana and tobacco;
>
> 3. Examine differences in self-administration of THC and nicotine from various combinations of marijuana and tobacco during ad libitum access.

This proposal will advance the field, providing one of the few experimental studies on marijuana-tobacco interaction, the first that manipulates both THC and nicotine dose. It will inform our understanding of why users co-use marijuana and tobacco and of potential health consequences related to simultaneous THC and nicotine intake.

Dr. Andrea Gomez, PhD, and colleagues at the Helen Wills Neuroscience Institute at University of California, Berkeley are conducting non-human research entitled: *"The Molecular and Cellular Basis of Psychedelic-Induced Synaptic Plasticity and Cognitive Flexibility*." Dr. Gomez provided the following summary of this research:

> Identifying the biological basis of how the brain maintains stability while allowing for the flexibility needed for learning continues to be a paramount challenge in neuroscience and is the primary focus of my RAPC-approved research. Of critical relevance are the long-lasting effects of psychedelics on plasticity, which are currently gaining scientific attention, along with growing expectations regarding their therapeutic potential to treat psychiatric disorders. Despite the rising interest from clinical and pharmaceutical fields, we currently do not understand how a single dose of psychedelics results in long-lasting changes in the brain. In this period of review, my lab reveals that biological changes at the RNA level – not at the level of DNA – is a crucial mechanism contributing to long-term psychedelic- induced changes in the brain. We have dedicated our efforts to the analysis of our data comprising the most extensive and highest read-depth study to date looking at the cell type-specific gene regulatory responses to psychedelics (>26 billion reads). Importantly, our data identifies the location for how plasticity can persist well beyond the presence of the drug. In conclusion, our efforts contribute to our long-term aim to pioneer the development of therapeutics to treat psychiatric and neurodegenerative disorders associated with defective neural plasticity.

Dr. Yih-Ing Hser, MD, PhD, and colleagues at the Semel Institute at University of California, Los Angeles are conducting human research entitled *"Randomized Controlled Pilot Trial of Extended-Buprenorphine vs. Sublingual Buprenorphine-naloxone in Rural Settings (RXR) (CTN-0102-XR).*" Dr. Hser provided the following abstract of this research:

> The purpose of this pilot study is to explore the feasibility, acceptability, and effectiveness of the injectable extended-release buprenorphine (XR-BUP) for treatment of opioid use disorder in rural settings, as compared to sublingual buprenorphine-naloxone (SL-BUP). This is a multi-site study that will be conducted in approximately seven (7) primary care clinics in rural areas across the United States, with one of those sites being in California. There is a continued need for improving delivery and outcomes of medication treatment for opioid use disorder (MOUD) in rural settings, including MOUD retention. Extended-release buprenorphine may offer an alternative to daily-dose formulations to facilitate retention and improve treatment outcomes among rural populations of individuals with opioid use disorder (OUD). The feasibility, acceptability, and effectiveness of the extended-release formulation of buprenorphine in rural settings is unknown. This study will explore these issues in rural settings to advance the knowledge base in a highly

impacted population – rural patients and in rural settings that have limited experience in use of extended-release buprenorphine.

Dr. William Jagust, MD, and colleagues at University of California, Berkeley are conducting human research entitled *"Dopaminergic Mechanisms Underlying Decision Making: Academic Human Subjects Research with Schedule II Drug (Methylphenidate)."* Dr. Jagust provided the following abstract of this research:

> Decision making involves strategies to learn how rewards occur, and to consider other individuals who are competing for the same rewards. Reward-related decisions are widely conjectured to involve the brain's dopamine system. Our project uses a strategic learning framework that examines performing a competitive social game. Measurement of dopamine is done using PET scanning with [11C]raclopride to measure baseline dopamine receptors and dopamine release in the face of a methylphenidate challenge. Our preliminary data indicate that dopamine release enhances effects on certain parameters reflecting strategic learning. Further analyses will extend and refine these initial observations.

Dr. Yi Zuo, PhD, and colleagues in the Department of Molecular, Cell, and Developmental Biology at University of California, Santa Cruz are conducting the non-human research project entitled *"Chemical Modulation of Neural Circuits and Plasticity."* Dr. Zuo provided the following abstract of this research:

> Psilocybin is both a potent hallucinogen and psychoplastogen, but whether these distinct effects share similar cellular mechanisms remains unclear. Using mouse models—an established system for studying psilocybin's mechanisms due to their well-characterized neural circuits and genetic manipulability—we found that psilocybin's psychoplastogenic effects rely on 5HT2AR expression in cortical layer 5 pyramidal neurons, while its hallucinogenic activity depends on 5HT2AR but involves different pathways. Our ongoing research investigates psilocybin's role in restoring synapses lost under stress, a major risk factor for psychiatric disorders. By comparing stressed and unstressed mouse brains, we aim to determine whether psilocybin normalizes neural function and behavior in stress conditions and how environmental context influences its effects. These findings will clarify the distinct pathways underlying psilocybin's hallucinogenic and therapeutic actions, advancing its application in stress- related disorders.

Dr. Deron Herr, PhD and Dr. Bradley Moore, PhD, and colleagues at Sanford Benham Prebys Medical Discovery Institute and University of California, San Diego are conducting non-human research entitled *"Biosynthesis and Biological Mechanism of Minor Cannabinoids."* Drs. Herr and Moore provided the following abstract of this research:

> Plant cannabinoids display high potential for the treatment of chronic pain, obesity, and neurodegenerative diseases. While well-known and abundant Phytocannabinoids such

as Delta-9-THC and cannabidiol (CBD) have largely been the focus of cannabinoid research to-date, minor products from *Cannabis sativa* and other producers have been overlooked for pharmacological studies simply due to low abundance and complex synthetic pathways. Thus, much remains to be learned about the pharmacological profile of minor cannabinoids. To evaluate the potential therapeutic benefits of more than 100 naturally-occurring minor cannabinoid products and analogues, we propose to develop new synthetic biology technology to rigorously produce structurally diverse cannabinoids and to investigate their biological targets by establishing the "cannabinoid-ome" of therapeutic receptors.

Dr. Robin Carhart-Harris, PhD, and colleagues from the Weill Institute for Neurosciences at University of California, San Francisco are conducting human research entitled *"Multivariate Neural and Physiological Correlates of Psychedelic Sub-states: A Within Subjects, Healthy Volunteer Study with Experience-Sampling. (Insight-2)."* Dr. Carhart-Harris provided the following abstract of this research:

Insight-2 uses multi-modal recordings of central (via fMRI) and peripheral physiology (via multimodal biosensing, MMBS), in combination with experience sampling, to create a model of the physiology of psychedelic sub- states for the purpose of detecting or decoding their presence in real-time data. The study aims to develop a data-driven model of valence-specific sub- states occurring within the broader psilocybin altered state of consciousness. We hypothesize that highly pleasant sub-states are important mediators of key long-term outcomes linked to psychedelic experiences, and their potential therapeutic application. Our ultimate goal is to identify sensitive and specific markers of pivotal sub-states in real-time that can inform real- time interventions within psychedelic therapy - a rapidly developing field of medicine. This upcoming calendar year we will be finishing data collection. We are on course to achieve this in 2025.

Dr. Stephen Mahler, PhD, and colleagues at University of California, Irvine are conducting human substance use disorder treatment research entitled *"Neural Circuits Underlying Motivation and Addiction."* Dr. Mahler provided the following abstract of this research:

The Mahler Lab seeks to understand why some individuals become addicted to drugs when they try them, and others do not. Addiction is a devastating disorder, and addiction to opioid drugs is particularly harmful to individuals and to society. We seek to uncover how developmental risk factors like early-life adversity and poverty-induced stress, or adolescent use of drugs like THC and nicotine may disrupt brain development in a way that can put individuals at persistent risk of becoming addicted to drugs if they try them later in life. Furthermore, we also seek to improve the translational relevance of our rodent research by developing new behavioral models of addiction in rats, in hopes of better capturing addiction-relevant behavioral phenomena in animals, of uncovering their precise neural substrates, and of leveraging this information to develop new treatment and prevention approaches for drug use disorders.

TABLE 1
RESEARCH STUDIES APPROVED IN 2024

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 (VSL-01-203)

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

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

Ryan Baxter, PhD | University of California, Merced | Merced, CA
Light Control and Oxidation Potential of Cannabinoids

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

Kevin Beier, PhD | University of California, Irvine | Irvine, CA
Reversing Maladaptive Plasticity Using Psilocybin

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

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 (BB- CAM-22-001)

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))

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA
High Potency Cannabis: Acute and Protracted Effects (Protocol #24-5316)

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 | Los Angeles, CA
Interactions Between Delta-9-THC and CBD: A Controlled Human Drug Administration Study Probing a Harm Reduction Strategy (Protocol #24-5306)

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 Mount Sinai School | New York, NY
Safety and Efficacy of High Dose BUP Induction in Fentanyl Positive Emergency Department Patients

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)

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

Jerel Fields, PhD | University of California, San Diego | La Jolla, CA
Cannabis and Pathogenic Mechanisms Influencing Blood Brain Barrier Function in HIV

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

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)

Deron Herr, PhD | Sanford Benham Prebys Medical Discovery Institute | La Jolla, CA
Biosynthesis and Biological Mechanism of Minor Cannabinoids

Yih-ing Hser, PhD | University of California, Los Angeles | Los Angeles, CA
Randomized Controlled Pilot Trial of Extended-Buprenorphine vs. Sublingual Buprenorphine-naloxone in Rural Settings (RXR) (CTN-0102-XR)

Hound Labs, Inc | Fremont, CA
Study to Evaluate Performance of the Hound Cannabis Breathalyzer - On Demand (OND 001)

Hound Labs, Inc | Fremont, CA
Study to Evaluate the Aging Process of Hound Cannabis Breathalyzer: Collect + Send Cartridges (CNS 004)

Incannex Healthcare | 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 (RePOSA)

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

Christina Kim, PhD | University of California, Davis | Davis, CA
Brainwide Molecular Profiling of Activated Neuronal Circuits

David E. Krantz, MD, PhD | University of California, Los Angeles | Los Angeles, CA
Serotonergic Signaling in Drosophila

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

LITES Network | University of Pittsburgh | Pittsburgh, PA
Prehospital Analgesia Intervention trial (PAIN Trial)

Stephen V. Mahler, PhD | University of California, Irvine | Irvine, CA
Therapeutic Effects of Psychedelic Drugs in Rats

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

Bradley S. Moore, PhD | University of California, San Diego | La Jolla, CA
Biosynthesis and Biological Mechanism of Minor Cannabinoids

Alysson Muotri, PhD | University of California, San Diego | La Jolla, CA
Mechanisms of Action of Psychedelics in Human Brain Organoids

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)

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)

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)

Jacobo Mintzer, MD | Medical University of South Carolina | Charlston, SC
Life's end Benefits of cannaBidiol and tetrahYdrocannabinol (LiBBY) (ATRI-007)

Leslie Morland, Psy.D | Veteran's Admin. San Diego Healthcare System | San Diego, CA
MDMA-Assisted Massed Prolonged Exposure for PTSD (IVAPT4)

National Institute on Drug Abuse (NIDA)/ Veteran's Administration | 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)

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

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)

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

Relmada Therapeutics, Inc. | Coral Gables, FL
A Randomized, Double-Blind Placebo-Controlled Trial of REL-1017 as an Adjunctive Treatment for Major Depressive Disorder (The RELIGHT Study)

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 (IUSOD1)

Gideon St. Helen, PhD | University of California, San Francisco | San Francisco, CA
Understanding the Clinical Pharmacology of Marijuana-Tobacco Co-Administration (CANNIC Study)

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 (BCSP02)

Gaia Skibinski, PhD | Herophilus, Inc. | San Francisco, CA
Pharmacological Effects of Controlled Substances in Cerebral Organoids

Patricia Suppes, MD, PhD | VA Palo Alto Healthcare System/Stanford University | 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)

Usona Institute | CRO: Worldwide Clinical Trials | 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)

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 (VX24-993-101)

Charles Wang, MD, PhD, MPH | Loma Linda University | Loma Linda, CA
Investigating Effects and Underlying Epigenomic Mechanisms Following Prenatal THC Exposure

Yale University/National Institute on Drug Abuse (NIDA) | New Haven, CT
ED-Initiated Standard Versus High Dose Buprenorphine Induction (ED-ENVISION) (CTN-0099)

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 (CTN- 0131)

TABLE 2

RESEARCH STUDIES AMENDED IN 2024

Beckley Psytech Ltd. | CRO: Worldwide Clinical Trials | 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)

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)

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)

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: Worldwide Clinical Trials | Morrisville, NC
Efficacy and Safety of COMP360 Psilocybin therapy in Anorexia Nervosa: A Proof-of-Concept Study (COMP 401)

Nicholas V. Cozzi, PhD | Alexander Shulgin Research Institute, Inc. (ASRI) | Berkeley, CA
Synthesis and Structure-Activity Relationships of Psychoactive Drugs Acting on Biogenic Amine Systems

Maxellende Ezin, PhD | Loyola Marymount University | Los Angeles, CA
Effects of Psilocybin on Embryonic Development

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

Inscopix | CRO: LifeSource Biomedical Services LLC | Moffett Field, CA
Investigation of the Impact of Psychedelic Compounds on Prefrontal Cortical Circuits

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

Peter Leeming, PhD | S & B Pharma LLC, dba Norac Pharma | Azusa, CA
Panel Approved Research Project (2)

LITES Network| University of Pittsburgh | Pittsburgh, PA
Prehospital Analgesia INtervention trial (PAIN)

Edythe London, PhD | University of California, Los Angeles | Los Angeles, CA
Cannabidiol Effects on Craving and Relapse Prevention in Opioid Use Disorder. (Previously: Cannabidiol as Adjunctive Treatment for Opioid Use Disorder)

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, Psy.D | Veterans Admin. San Diego Healthcare System | San Diego, CA
MDMA-Assisted Massed Prolonged Exposure for PTSD (IVAPT4)

Leslie Morland, PsyD | VA San Diego Healthcare System | San Diego, CA
MDMA-Assisted Brief Cognitive Behavioral Conjoint Therapy for PTSD (IVAPT2)

National Institutes of Drug Abuse (NIDA) | CRO: The Emmes Company | Rockville, MD
Emergency Department-Initiated Buprenorphine Validation Trial (ED-INNOVATION) (CTN-0099)

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

Relmada Therapeutics, Inc. | Coral Gables, FL
A Randomized, Double-Blind Placebo-Controlled Trial of REL-1017 as an Adjunctive Treatment for Major Depressive Disorder (The RELIGHT Study)

Relmada Therapeutics, Inc. | Coral Gables, FL
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (RELIANCE-II)

Usona Institute | CRO: Worldwide Clinical Trials | 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)

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 (VX24-993-101)

Marc Weintraub, PhD | University of California, Los Angeles | Los Angeles, CA
Psilocybin - Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

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

Yale University| Research Group at Yale (SNRGY) | West Haven, CT
Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

Yale University and 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 (CTN- 0131)

Fadel Zeidan, PhD | University of California, San Diego | La Jolla, CA
Brain Mechanisms of Cannabis-Based Analgesia

TABLE 3
RESEARCH STUDIES CLOSED IN 2024

Stephan Anagnostaras, PhD | University of California, San Diego | La Jolla, CA
MDMA and Memory, Addiction, Social Behavior, Anxiety, and Depression:
A Dose-Effect Analysis

Nick Andrews, PhD | Salk Institute | La Jolla, CA
Effect of the Psychedelic Class of Pharmaceuticals in Preclinical Models of Chronic Pain

Avadel | CRO: Advanced Clinical | Deerfield, IL
An Open Label Study to Evaluate Long-Term Safety and Tolerability of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) and the Ability to Switch from Twice- Nightly Immediate-Release Sodium Oxybate to Once-Nightly FT (CLFT218-1901)

Ryan Baxter, PhD | University of California, Merced | Merced, CA
Cannabinoid Isolation, Purification, and Structure Diversification

Phillip Coffin, MD | San Francisco Department of Public Health | San Francisco, CA
Phase 1 Safety-Interaction Study of Mirtazapine for the Treatment of Methamphetamine Use Disorder

Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Morrisville, NC
Efficacy and Safety of COMP360 Psilocybin therapy in Anorexia Nervosa: A Proof-of-Concept Study (COMP 401)

Nicholas V. Cozzi, PhD | Alexander Shulgin Research Institute, Inc. (ASRI) | Berkeley, CA
Synthesis and Structure-Activity Relationships of Psychoactive Drugs Acting on Biogenic Amine Systems

Stephen Derman, CIH, FAIH, | Parc, a Xerox Company | Palo Alto, CA
Roadside Drug Detection

Ryan Hibbs, PhD | University of California, San Diego | La Jolla, CA
Use of Methaqualone in Structural Biology Research

Keith Heinzerling, MD | Pacific Neuroscience Institute | Santa Monica, CA
Pilot trial of Visual Healing®, a Nature-Themed Virtual Immersive Experience, to Optimize Set and Setting in Psilocybin-Assisted Therapy for Alcohol Use Disorder

Hound Labs, Inc | Fremont, CA
Study to Evaluate the Aging Process of Hound Cannabis Breathalyzer: Collect + Send Cartridges (CNS 004)

William Jagust, MD | University of California, Berkeley | Berkeley, CA
Dopaminergic Mechanisms Underlying Decision-Making: Academic Human Subjects Research with Schedule II Drug (methylphenidate)

Christina Kim, PhD | University of California, Davis | Davis, CA
Brainwide Molecular Profiling of Activated Neuronal Circuits

Charles Lee, PhD | USDA-ARS | Albany, CA
Low THC Industrial Hemp Cultivars

Edythe London, PhD | University of California, Los Angeles | Los Angeles, CA
Cannabidiol Effects on Craving and Relapse Prevention in Opioid Use Disorder. (Previously: Cannabidiol as Adjunctive Treatment for Opioid Use Disorder)

Svetlana Nikoulina, PhD | Pharmaron with Navinta LLC| San Diego, CA
Evaluation of Pharmacokinetic Parameters of Sponsor's Test Article(s) Containing THC after Intranasal (IN), Intravaginal (IVG) and Oral (PO) Administration in Female Beagle Dogs (Crossover)

Relmada Therapeutics, Inc. | Coral Gables, FL
A Randomized, Double-Blind Placebo-Controlled Trial of REL-1017 as an Adjunctive Treatment for Major Depressive Disorder (The RELIGHT Study)

Relmada Therapeutics, Inc. | Coral Gables, FL
A Phase 3, Multicenter, Open-Label Study to Assess the Long-Term Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (RELIANCE-OLS)

Relmada Therapeutics, Inc. | Coral Gables, FL
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (RELIANCE-II)

Nathaniel M. Schuster, MD | University of California, San Diego | La Jolla, CA
Inhaled Cannabis Versus Placebo for the Acute Treatment of Migraine: A Pilot, Randomized, Double- blind, Placebo-Controlled, Cross-over, Dose-Ranging Trial

Nathaniel M. Schuster, MD | University of California, San Diego | La Jolla, CA
Efficacy of Inhaled Cannabis Versus Placebo for the Acute Treatment of Migraine: A Randomized, Double-Blind, Placebo-Controlled, Crossover Trial

Skye Bioscience, Inc. | San Diego, CA
A Phase 2, Double-Masked, Randomized, Vehicle-Controlled, Dose-Response Study Assessing the Safety and Ocular Hypotensive Efficacy of Two Concentrations of SBI-100 Ophthalmic Emulsion in Patients with Elevated Intraocular Pressure (SBI-100-201)

InterveXion Therapeutics | San Diego, CA
OUTLAST: A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety and Efficacy of IXT-m200 in Treatment-Seeking Individuals with Methamphetamine Use Disorder

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA
Panel Approved Research Project (1)

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA
Panel Approved Research Project (2)

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA
Panel Approved Research Project (3)

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA
Panel Approved Research Project (4)

Jeff Ubersax, PhD | Demetrix, Inc. | Emeryville, CA
Production of Natural and Modified Cannabinoids using Engineered, Industrial Microorganisms

Vertex Pharmaceuticals, Inc. | CRO: ICON Global Strategic Solutions | Boston, MA
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After a Bunionectomy (VX22-548-104)

Vertex Pharmaceuticals, Inc. | CRO: ICON Global Strategic Solutions | Boston, MA
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain After an Abdominoplasty (VX22-548-105)

Jennifer Wenzel, PhD | University of San Diego | San Diego, CA
The Effects of Adolescent Cannabinoid Exposure on Cocaine Reward and Aversion

Brandon Zipp, PhD | Graphium Biosciences, Inc. | Rocklin, CA
Panel Approved Research Study

APPENDIX A

OPEN (THROUGH DECEMBER 31, 2024)
SCHEDULE I AND SCHEDULE II
ACADEMIC AND INDEPENDENT HUMAN RESEARCH STUDIES

Catherine Ayers, PhD and Brian Martis, MD | San Diego Veterans Affairs Med | 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 Bershad, MD, PhD | University of California, Los Angeles | Los Angeles, CA
Tolerability of MDMA in Schizophrenia

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

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

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 (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)

Ziva Cooper, PhD | University of California, Los Angeles | 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 | 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
Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences Between Men and Women

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA
High Potency Cannabis: Acute and Protracted Effects (Protocol #24-5316)

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 | Los Angeles, CA
Interactions Between Delta-9-THC and CBD: A Controlled Human Drug Administration Study Probing a Harm Reduction Strategy (Protocol #24-5306)

Randall Espinoza, MD, MPH | University of California, Los Angeles | Los Angeles, CA
Psilocybin Pilot for Treatment-Resistant Depression (TRD)

Timothy Furnish, MD | University of California, San Diego | San Diego, CA
Behavioral and Neural Mechanisms Supporting Psilocybin Assisted Therapy for Phantom Limb Pain

Brook Henry, PhD | University of California, San Diego | San Diego, CA
Cannabis Effects on Antiretroviral Therapy Pharmacokinetics and Neurotoxicity

David Hessl, PhD | University of California, Davis | Sacramento, CA
Randomized Controlled Trial of Quillivant in Intellectual Disability with ADHD

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 | Veteran's Admin. San Diego Healthcare System | San Diego, CA
MDMA-Assisted Massed Prolonged Exposure for PTSD (IVAPT4)

Leslie Morland, PsyD | VA 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, MPH| University of California, San Francisco | San Francisco, CA
Study of Psilocybin for the Treatment of Anorexia Nervosa in Young Adults

Shannon Remick, MD | VA 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 (IUSOD1)

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 (BCSP01)

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 (BCSP02)

Gideon St. Helen, PhD | University of California, San Francisco | San Francisco, CA
Understanding the Clinical Pharmacology of Marijuana-Tobacco Co-Administration (CANNIC Study)

Trisha Suppes, MD, PhD | VA Palo Alto Health Care System | Palo Alto, CA
The Safety and Efficacy of Psilocybin in Participants with Severe Treatment-Resistant Depression (P- TRD)

Patricia Suppes, MD, PhD | VA Palo Alto Healthcare System/Stanford University | 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)

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

Fadel Zeidan, PhD | University of California, San Diego | La Jolla, CA
Brain Mechanisms of Cannabis-Based Analgesia

APPENDIX B

OPEN (THROUGH DECEMBER 31, 2024)
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 (VSL-01-203)

Beckley Psytech Ltd. | Worldwide Clinical Trials | 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)

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)

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 (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)

Hound Labs, Inc | Fremont, CA
Study to Evaluate Performance of the Hound Cannabis Breathalyzer - On Demand (OND 001)

Incannex Healthcare | 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 (RePOSA)

LITES Network | University of Pittsburgh | Pittsburgh, PA
Prehospital Analgesia INtervention trial (PAIN)

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)

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)

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)

Jacobo Mintzer, MD | Medical University of South Carolina | Charlston, SC
Life's end Benefits of cannaBidiol and tetrahYdrocannabinol (LiBBY) (ATRI-007)

Usona Institute | CRO: Worldwide Clinical Trials | 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)

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 (VX24-993-101)

Yale University| Research Group at Yale (SNRGY) | West Haven, CT
Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

APPENDIX C

OPEN (THROUGH DECEMBER 31, 2024)
CONTROLLED SUBSTANCE USE DISORDER TREATMENT
RESEARCH STUDIES

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 (BB- CAM-22-001)

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 Mount Sinai School | New York, NY
Safety and Efficacy of High Dose BUP Induction in Fentanyl Positive Emergency Department Patients

Yih-ing Hser, PhD | University of California, Los Angeles/ National Institute on Drug Abuse (NIDA) | Los Angeles, CA
Randomized Controlled Pilot Trial of Extended-Buprenorphine vs. Sublingual Buprenorphine-naloxone in Rural Settings (RXR) (CTN-0102-XR)

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

National Institute on Drug Abuse (NIDA) | CRO: The Emmes Company | Rockville, MD
Optimizing Retention, Duration and Discontinuation Strategies for Opioid Use Disorder Pharmacotherapy (RDD) (CTN-100)

National Institute on Drug Abuse (NIDA) | 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) (CTN-0109)

National Institute on Drug Abuse (NIDA) | CRO: The Emmes Company | Rockville, MD
Emergency Department-Initiated Buprenorphine Validation Trial (ED-INNOVATION) (CTN-0099)

National Institute on Drug Abuse (NIDA)/ Veteran's Administration | 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)

Yale University/National Institute on Drug Abuse (NIDA) | New Haven, CT
ED-Initiated Standard Versus High Dose Buprenorphine Induction (ED-ENVISION) (CTN-0099)

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 (CTN- 0131)

APPENDIX D

OPEN (THROUGH DECEMBER 31, 2024)
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 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

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

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 Corp. with Usona Institute | San Luis Obispo, CA
Development of Tools and Technologies Toward Understanding the Mechanism of Action, Safety, and Therapeutic Potential of Psychedelic Compounds

Cesear Corona, PhD | Promega Corp. with 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

Nissar Darmani, PhD | Western University Health Sciences | Pomona, CA
Project 1: Mechanisms of Vomiting Induced by Chemotherapeutics, Related Emetics, and GI Disorders

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 Destaillats, 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

Davide Dulcis, PhD | University of California, San Diego | La Jolla, CA
Effects of Neonatal Nicotine Exposure on Dopamine Neurons

Maxellende Ezin, PhD | Loyola Marymount University | Los Angeles, CA
Effects of Psilocybin on Embryonic Development

Torsten Fiebig, PhD | CARI Health | San Diego, CA
DPV Assay of Racemic Methadol in Variable Biomatrices

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

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

Andrea Gomez, PhD | University of California, Berkeley | Berkeley, CA
The Molecular and Cellular Basis of Psychedelic-Induced Synaptic Plasticity and Cognitive Flexibility

Adam Halberstadt, PhD | University of California, San Diego | La Jolla, CA
The Next Generation of Hallucinogens: A New Class of Synthetic Psychoactive Drugs

Boris 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 Kutyrev, 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
Panel Approved Research Study (1)

Peter Leeming, PhD | S&B Pharma LLC (dba Norac Pharma) | Azusa, CA
Panel Approved Research Study (2)

Byungkook Lim, PhD | U.C. 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
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
Molecular and Circuit Effects of Psychedelic Drugs on the Central Nervous System

Pamela A. Maher, PhD | Salk Institute | La Jolla, CA
Therapeutic Relevance of Cannabinoids for Alzheimer's Disease

Stephen Mahler, PhD | University of California, Irvine | Irvine, CA
Neural Circuits Underlying Motivation and Addiction

Stephen V. Mahler, PhD | University of California, Irvine | Irvine, CA
Therapeutic Effects of Psychedelic Drugs in Rats

Robert Malenka, MD, PhD | Stanford University | Palo Alto, CA
The Role of Oxytocin in the Pathogenesis of Autism

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

Christopher Moxham, PhD | Rarebase | Palo Alto, CA
Profiling the Transcriptomic Response of Select Controlled Substances in Vitro

Bradley S. Moore, PhD | University of California, San Diego | La Jolla, CA
Biosynthesis and Biological Mechanism of Minor Cannabinoids

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

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

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 Generic and Acquired Epilepsy

Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA
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Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA
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Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA
Effect of Adolescent Cannabis Exposure in Adult Mice and Rats In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

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

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

Matthew Springer, PhD | University of California, San Francisco | San Francisco, CA
Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers

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

Yi Tang, PhD | University of California, Los Angeles | Los Angeles, CA
Synthetic Biology Approaches to Cannabinoid Diversification and Production

Francesca Telese, PhD | University of California, San Diego | La Jolla, CA
Epigenetic Regulation of Gene Expression in the Brain

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 Study

Kay Tye, PhD | Salk Institute | 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 | La Jolla, CA
Assessment of Changes in Behavioral and Neural Correlates of Social and Physical Pain Processing Produced by Tetrahydrocannabinol (THC)

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

Charles Wang, MD, PhD, MPH | Loma Linda University | Loma Linda, CA
Investigating Effects and Underlying Epigenomic Mechanisms Following Prenatal THC Exposure

Joseph Wu, MD, PhD | Stanford University | Stanford, CA
Human iPSCs for Elucidating Cardiovascular Risks of Cannabis

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

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

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 FROM THE CALIFORNIA HEALTH AND SAFETY CODE

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 physician, or a person holding a doctorate degree in the health sciences, a representative of a private

(Section 11480 Cont.)

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 outcomes.

(Section 11362.9 Cont.)

(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:

(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.

(Section 11362.9 Cont.)

(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.

(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.

(Section 11362.9 Cont.)

(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.

(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.

(Section 11362.9 Cont.)

(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 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

(Section 11362.9 Cont.)

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.

(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

(Section 11839.3 Cont.)

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 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

(Section 11839.3 Cont.)

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 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.

(Section 11839.7 Cont.)

(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 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

(Section 11839.7 Cont.)

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.

(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:

(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.

(Section 24173 Cont.)

(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

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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.

(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.

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(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).

(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

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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.

(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.

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(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.

(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.

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(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.

(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

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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:

(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,

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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.

(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.

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(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.

(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

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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 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

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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)