2023

Research Advisory Panel of California

RAPC
RESEARCH ADVISORY PANEL OF CALIFORNIA

53rd Annual Report to the Governor and Legislature of California

Research Advisory Panel of California
455 Golden Gate Avenue - Suite 11000
San Francisco, California 94102-7004
https://oag.ca.gov/research
Email contact: RAPC@doj.ca.gov

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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.

RESEARCH ADVISORY PANEL OF CALIFORNIA

2023 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.

Enid Camps, JD
Deputy Attorney General, State of California Office of the Attorney General, San Francisco
Panel Chair, Appointed by the California State Attorney General
(Through October 26, 2023)

Martine D'Agostino, JD
Deputy Attorney General, State of California Office of the Attorney General, Oakland
Appointed by the California State Attorney General
(From October 27, 2023)

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

James J. Gasper, PharmD, BCPP
Psychiatric and Substance Use Disorder Pharmacist, CA. Dept. of Health Care Services
Appointed by the California Department of Public Health

Boriss Heifets, MD, PhD
Assistant Professor, Stanford University School of Medicine
Appointed by Stanford University

Andrew S. Kayser, MD, PhD
Professor of Neurology, UCSF School of Medicine
Appointed by the University of California
(Through November 29, 2023)

Jennifer Mitchell, PhD
Professor of Neurology and Psychiatry and Behavioral Sciences, UCSF School of Medicine
Associate Chief of Staff for Research and Development, San Francisco Veterans Administration Medical Center (SFVAMC)
Appointed by the California State Governor

RAPC Staff

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

2023 SUMMARY OF ACTIVITIES

During calendar year 2023, the Research Advisory Panel of California (RAPC) reviewed 49 new and 53 substantively amended applications. Of these, RAPC approved 21 new studies and 40 amended applications for 27 studies. Twelve new studies from 2022 also received RAPC approval in 2023. Due to a procedural issue that affected RAPC panel meetings in 2023, RAPC completed review and approval of the remaining applications in 2024. That procedural issue was resolved with the passage of Assembly Bill 2841 on July 18, 2024.

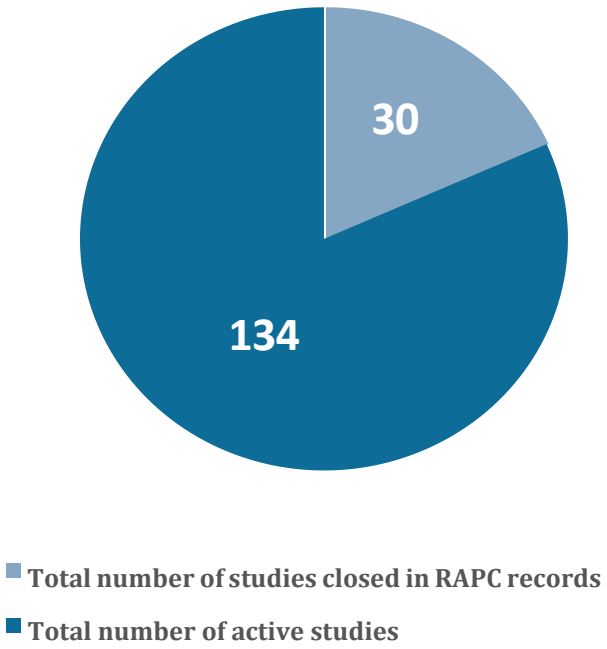
The 2024 Annual Report will include the 24 new and six amended studies from 2023 approved in 2024. These approvals can also be found in the addendum following this report.

Thirteen new human research studies were approved in 2023: Eight were clinical drug trials, three were academic or independent studies, and two were substance use disorder treatment studies. Twenty non-human research projects were approved by RAPC. Thirty studies were completed or terminated in 2023 and closed in RAPC records (figure 1).

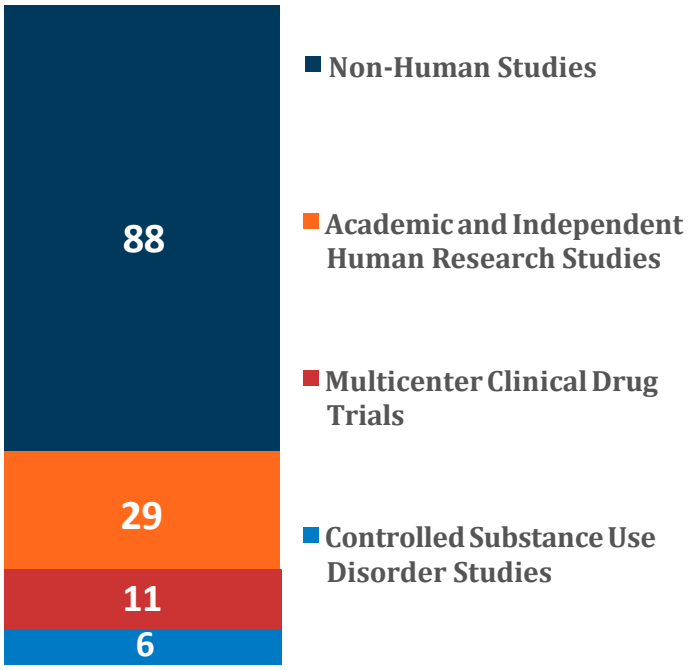
Table 1 in this report tabulates the new studies approved in 2023. Table 2 lists amended studies approved during this same time period. Table 3 represents studies completed or terminated in 2023 and closed in RAPC records. At the end of 2023, RAPC was monitoring 134 active studies (for a breakdown, see figure 2). Please 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. No site visits were performed in 2023. RAPC approval may be withdrawn if study activities deviate substantively from the approved protocol.

2023 ACTIVE AND CLOSED STUDIES (fig. 1)



2023 ACTIVE STUDIES BY TYPE (fig. 2)



SELECTED RESEARCH FINDINGS

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

Dr. Edythe London, PhD, and colleagues at the UC Los Angeles Semel Institute for Neuroscience & Human Behavior are conducting human substance use disorder treatment research entitled *"Cannabidiol Effects on Craving and Relapse Prevention in Opioid Use Disorder."* Dr. London has provided the following abstract of this research:

> Opioid Use Disorder (OUD), involving prescription opioids or heroin, is a public health emergency leading to unprecedented drug-related mortality in the United States, underscoring the need for innovative medical treatments for OUD. Opioid receptor agonist and antagonist medications are currently available for treatment of OUD. Of the opioid agonists used, buprenorphine has a more favorable safety profile than methadone, but retention in treatment is low for both medications. The opioid antagonist naltrexone is also used for patients with OUD, but it has even lower adherence rates.
>
> Positive findings from preclinical and clinical studies provide a rationale for the use of cannabidiol (CBD) in this clinical trial. In animal models, CBD has behavioral effects suggesting that CBD may offer benefit in relapse prevention for patients with OUD. These effects include the attenuation of opioid reward, conditioned reinstatement of opioid-seeking behavior, stress-induced drug seeking and reductions in anxiety- and impulsivity-like behaviors. Moreover, a Phase 2, randomized, double-blind, placebo-controlled, pilot study found that a single dose of CBD (400 or 800 mg) decreased cue-induced opioid craving and blunted anxiety.
>
> Although promising findings suggest that CBD can reduce craving and anxiety and attenuate opioid-related reward, rigorous clinical trials are needed to establish the full potential and determine the optimal dosage of CBD as adjunctive therapy for OUD. This is the background and rationale for this study. The goal of this research is to evaluate cannabidiol (CBD) as an adjunctive treatment to buprenorphine (transmucosal buprenorphine formulations, e.g., buprenorphine + naloxone) in patients with OUD receiving residential treatment.
>
> This study is a randomized, double-blind, placebo-controlled study of ATL5 (CBD) (600 mg/day, [300 mg twice daily] vs. placebo) as adjunctive therapy to buprenorphine for patients with OUD receiving inpatient behavioral therapy, including cognitive behavioral therapy, in a residential facility. The primary endpoint is safety and tolerability of CBD, assessed via measurement of cardiovascular parameters, other vital signs, liver enzymes, pulse oximetry, adverse events, and pharmacokinetics. Pharmacokinetic analyses will evaluate potential drug-drug interactions of CBD with buprenorphine metabolism.

The secondary outcome measure will be cue-induced craving for opioids, assessed using the Desires for Drug Questionnaire (DDQ) in the context of an opioid cue-induction paradigm in a laboratory session at baseline and on Days 7 and 28 of treatment. Future studies may comprise outpatient clinical trials of CBD as adjunctive therapy to buprenorphine, and an exploratory evaluation of CBD vs. naltrexone as a monotherapy in patients with OUD to prevent relapse. Success in this project can reduce opioid–related deaths by providing a medication that will prevent relapse to opioid use, which puts individuals with OUD at risk for death from an opioid overdose.

Dr. Marc Weintraub, PhD, and colleagues at the UC Los Angeles Semel Institute for Neuroscience & Human Behavior are conducting the human research project entitled *"Psilocybin-Assisted Cognitive Behavioral Therapy for Major Depressive Disorder."* Dr. Weintraub has provided the following abstract of this research:

Recent studies suggest that one to two administrations of psilocybin have acute antidepressant effects for persons with major depressive disorder. These data on psilocybin have generated considerable enthusiasm, but little empirical attention has been paid to the therapy that adjoins psilocybin treatment (psychedelic-assisted therapy, or PAT). In this study, we present the initial protocol and plans to empirically test the psychosocial therapy that adjoins psilocybin treatment with the goal of optimizing this therapeutic approach for adults with major depressive disorder. The psychotherapy is based on the principles of cognitive-behavioral therapy (CBT), an evidence-based treatment for major depressive disorder. Participants will be 30 adults with a history of major depressive disorder and current, active depressive symptoms. Following psychiatric and medical safety evaluations, eligible participants will be enrolled in a 12-session CBT that includes classic PAT safety elements (PA-CBT) over 4 months (9 weekly sessions followed by 3 biweekly sessions).

Following the third and sixth PA-CBT sessions, participants will engage in two psilocybin drug administration sessions (10 mg and 25 mg, respectively). Participants will provide feedback about the PA-CBT and complete measures of mood symptoms, psychosocial functioning, cognitive schemas, and affective experiences immediately following each drug administration session, at the completion of PA-CBT, and three months following treatment completion. The trial will provide preliminary data on the feasibility, safety, acceptability, and psychosocial effects of PA-CBT. Findings will provide evidence to support a recommendation regarding the safety and feasibility of future randomized clinical trials to test the effects of PA-CBT for patients with depression and other mental health conditions, as well as data on mediating mechanisms at the cognitive and affective levels.

Dr. Scott Wilke, MD, PhD, and colleagues at the UC Los Angeles TMS Clinic and Research Program are conducting human research entitled "*Psychostimulant Augmentation of Repetitive TMS (rTMS) for the Treatment of Major Depressive Disorder: a Randomized, Placebo-controlled Clinical Trial.*" Dr. Wilke has provided the following abstract of this research:

Our objective in this study is to examine the effects of Adderall XR (generic, amphetamine salts) compared to placebo on rTMS treatment outcomes during the initial two weeks in a randomized, placebo-controlled clinical trial. We hypothesize that Adderall XR will be well- tolerated and will be associated with significantly earlier and greater improvement in depressive symptoms during an acute course of FDA-approved, clinical rTMS treatment.

Participants will be assigned by chance to active or placebo group. The active group will be asked to take one 15 mg pill once daily of Adderall XR (amphetamine) and the placebo group will be asked to take an identical appearing tablet/capsule, one tablet by mouth daily. The placebo tablet has no active ingredients and has no effect on the body or mind. With the exception of the study drug, all other study activities between both groups will be identical. Participants will use the assigned study drug two weeks before therapy and throughout the first 10 therapy treatments. A total of seven (7) visits will be required for screening, drug assignment, and completion of mood assessments.

Dr. Loren Looger, PhD, and colleagues from the Howard Hughes Medical Institute at UC San Diego are conducting several non-human research projects, including *"Molecular and Circuit Effects of Psychedelic Drugs on the Central Nervous System*," and *"Development of Fluorescent Sensors for Psychedelic Drugs."* Dr. Looger provided the following summary of his research:

The Looger Lab at the University of California, San Diego works on a wide range of projects, mostly of a cellular and molecular nature. We are undertaking several projects specifically aimed at elucidating the molecular mechanisms of psychedelic drugs using cells and model organisms. Here are short lay summaries of each major project:

1. We are trying to discover poorly understood molecular pathways that the drugs affect, beyond the canonical interactions with the serotonin receptor – which is the heart of most studies on these drugs. We have shown that these drugs modulate core biochemical pathways in cells, such as the function of serotonin, dopamine, etc. at protein targets other than the receptors. We think that these non-receptor interactions might play large roles in the long-lasting functions of these molecules.

2. We are trying to map the downstream effects of the drugs, regardless of where their primary interactions are (i.e., at the receptors or other targets). Given the extremely long-lasting nature of the effects of these drugs, we hypothesize that the drugs produce long-lived structural effects in the nucleus, extracellular space, and other locations. We are mapping these effects at the level of individual proteins and high-resolution cellular ultrastructure.

3. We are making tools for the systematic study of the trafficking of these drugs in neurons and animals. We are making genetically encoded fluorescent biosensors that can be expressed in particular places and light up when the drugs of interest arrive, and then go dim again when the drugs are trafficked away or metabolized. These tools will be broadly useful for determining the pharmacokinetics of these drugs in intact preparations.

Dr. Judith Hellman, MD, and colleagues from the Department of Anesthesia and Perioperative Care at UC San Francisco are conducting non-human research entitled "*Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury*." Dr. Hellman has provided the following abstract of this research:

> Our laboratory has a broad focus on understanding the role of the endocannabinoid system in immune function, and in responses to and outcomes of infections, inflammation, and injury. The host's endocannabinoid system is composed of multiple lipids mediators, known as endocannabinoids, as well as protein receptors for endocannabinoids and Cannabis derived cannabinoids. The endocannabinoid system plays roles in regulating neurological and psychological functions, vascular reactivity, blood pressure, and temperature. There is increasing evidence that cannabinoids have anti-inflammatory effects. We hypothesize that the endocannabinoid system plays a substantial role in the host's responses to injury and infection.
>
> In 2020 we reported in the *Journal of Immunology* that Delta 9-Tetrahydrocannabinol (THC) has strong anti-inflammatory actions in mice with acute inflammation or bacterial infection. We determined that the anti-inflammatory effects were mediated by cannabinoid receptor 1 (CB1R), and that THC improved functional outcomes of mice with acute inflammation. We are continuing to study the effects of THC *in vitro* in cultured cells, and *in vivo* in models of infection and injury. Our goal is to understand the immune effects of THC, as well as the effects of THC on inflammation and dysfunction of different cell populations (e.g., leukocytes, neurons, vascular endothelial cells), in different tissues (e.g., nervous system, systemic organs) during infection and acute inflammation. Additionally, the results of these studies should provide insight into the basic role of the endocannabinoid system and CB1R in infection and injury, which could lead to the identification of therapeutic targets within the endocannabinoid system.

Dr. Jacob Vogan, PhD, and colleagues at CB Therapeutics are conducting non-human research entitled "*Laboratory Scale Biosynthesis of Psilocybin in Baker's Yeast*" and "*Laboratory Scale Biosynthesis of DMT and Related Substituted Tryptamine Compounds in Baker's Yeast*." Dr. Vogan has provided the following abstract of this research:

> CB Therapeutics (CBT) is a research organization that develops novel biosynthetic approaches to sustainably supply and develop clinically relevant compounds to combat the growing mental health crisis, including depression, anxiety, and drug addiction. Of particular note, molecules such as tryptamines, which can also fall into the category of powerful psychedelic medicines, have gained renewed interest for clinical research into treating mental disease and increasing wellbeing. Our research efforts have led to developing a yeast fermentation platform for drug discovery, in a fashion similar to bread or winemaking, which can generate tryptamines such as the important neurotransmitters, serotonin and melatonin in scalable fermenters using cheap feedstocks. Related to these molecules, are potent tryptamines such as psilocybin and DMT which we have been exploring for sustainable biosynthesis,

along with methods to generate analogs for approved clinical research. From ongoing bioprospecting and strain engineering work, we have continued to discover and engineer genes that can efficiently carry out the biosynthesis steps of important tryptamine molecules in our yeast production platform. Our work will allow clinicians to access new medicines such as uniquely substituted tryptamines using biomanufacturing.

Dr. Melissa Bauman, PhD, and colleagues at the MIND Institute at UC Davis are conducting non-human research entitled "*Neurodevelopmental Impact of Prenatal Cannabis Exposure*." Dr. Bauman has provided the following summary of this research:

With the legalization of recreational marijuana in California in 2016, rates of use in pregnant women have been rising. Cannabis, commonly known as marijuana, is a product of the *Cannabis sativa* plant. The active compounds from this plant are collectively referred to as cannabinoids, which include a psychoactive cannabinoid, Delta, 9- tetrahydrocannabinol (THC). There is substantial evidence that THC crosses the placenta, and that it has effects on brain development and long-term effects on non-social cognition. Studies in humans prenatally exposed to cannabis have yielded inconsistent findings, which have potentially contributed to the belief among some cannabis users that smoking marijuana during pregnancy is safe. Even less is known about the impact of alternative methods for cannabis exposure (e.g., vaping) that have become more popular in the wake of U.S. cannabis legalization. Despite these concerns, there is a pronounced lack of studies on long-term, developmental effects of cannabis on species-typical social development. Our goal of this exploratory pilot project is to establish a translationally relevant preclinical model of prenatal THC exposure.

Dr. Pamela Maher, PhD, and colleagues at the Salk Institute for Biological Studies are conducting non-human research entitled "*Therapeutic Relevance of Cannabinoids for Alzheimer's Disease*." Dr. Maher provided the following summary of this research:

The oxytosis/ferroptosis regulated cell death pathway is an emerging field of research owing to its pathophysiological relevance to a wide range of neurological disorders, including Alzheimer's and Parkinson's diseases and traumatic brain injury. Developing novel neurotherapeutics to inhibit oxytosis/ferroptosis offers exciting opportunities for the treatment of these and other neurological diseases. Previously, we discovered cannabinol (CBN) as a unique, potent inhibitor of oxytosis/ferroptosis by targeting mitochondria and modulating their function in neuronal cells. To further elucidate which key pharmacophores and chemical space are essential to the beneficial effects of CBN, we herein introduce a fragment-based drug discovery strategy in conjunction with cell-based phenotypic screens using oxytosis/ferroptosis to determine the structure-activity relationship of CBN. The resulting information led to the development of four new CBN analogs, CP1-CP4, that not only preserve the submicromolar potency of neuroprotection and mitochondria-modulating activities seen with CBN in neuronal cell models but also have better druglike properties. Moreover, compared to CBN, the analog CP1 shows

improved in vivo efficacy in the Drosophila model of mild traumatic brain injury.

Together these studies identify the key molecular scaffolds of cannabinoids that contribute to neuroprotection against oxytosis/ferroptosis. They also highlight the advantageous approach of combining in vitro cell-based assays and rapid in vivo studies using Drosophila models for evaluating new therapeutic compounds.

Dr. Stephan Anagnostaras, PhD, and colleagues at UC San Diego are conducting non-human research entitled "*MDMA and Memory, Addiction, Social Behavior, Anxiety, and Depression: A Dose-Effect Analysis*." Dr. Anagnostaras has provided the following abstract of this research:

This project aims to pre-clinically evaluate the potential therapeutic psychiatric effects of MDMA versus potential adverse effects. We examine MDMA's ability to enhance social behavior, reduce anxiety and depression, and determine if these beneficial effects can be dissociated from its propensity to induce amnesia or addiction. Through this research, we may determine how and when MDMA may be useful in treating certain difficult-to-treat psychiatric conditions and how to avoid potentially serious adverse effects, namely amnesia and addiction.

Dr. Vikaas Sohal, MD, PhD, and Colleagues at UC San Francisco Weill Institute for Neurosciences are conducting non-human research entitled *"Investigating Brain Circuits that Underlie Potentially Therapeutic Psychedelic Drugs."* Dr. Sohal has provided the following abstract of this research:

There is currently a great deal of excitement about using psychedelic drugs including psilocybin to treat various neuropsychiatric disorders. However, these efforts are complicated by several issues – specifically, we do not have a good understanding of the behavior effects of these drugs, nor of how they act. Furthermore, psychedelic drugs carry serious risks including triggering and/or exacerbating psychotic disorders in a vulnerable subset of the population. Understanding the specific behavioral effects and neural mechanisms engaged by psychedelic drugs would help to ensure these are being used appropriately and could lead to the development of newer, more targeted therapies that maximize potential benefits while mitigating risks. A first step in this process is identifying robust and reliable behavioral effects of drugs such as psilocybin in animal models. Our laboratory at UCSF is currently performing multiple behavioral assays in coordination with other laboratories at UCSF, UC Berkeley and Stanford, to identify behavioral effects that are consistent and reproducible across sites. We have measured both acute and persistent (lasting 24 hours) effects of psilocybin, delivered at varying time points relative to different behavioral tests. Our initial findings include that the acute administration of psilocybin increases the avoidance of new anxiety-provoking spaces while also reducing freezing in a location where animals previous received a mild food shock. When animals are searching for hidden food rewards, acute psilocybin also increases behavior that deviates from previously learned strategies. Our next steps will be to confirm and extend these initial behavioral findings while also beginning to study the underlying brain circuit mechanisms.

TABLE 1

RESEARCH STUDIES APPROVED IN 2023

AnaBios Corporation, with Columbia University | San Diego, CA
Evaluating the Effect of Ibogaine HCl on Human Dorsal Root Ganglion (DRGs) Neurons

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

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

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

Compass Pathfinder Limited | CRO: Worldwide Clinical Trials, Inc | Morrisville, NC
A Phase II, Multicenter, Randomized, 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, Multicenter, 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, Multicenter, Randomized, Double-Blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants with Treatment-Resistant Depression (COMP 006)

Cesear Corona, PhD | Promega Corporation 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 Corporation 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

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

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

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

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

Daniela Kaufer, PhD | UC Berkeley | Berkeley, CA
Unraveling Biological Mechanisms of Psychedelic Medicine Using Preclinical Models of PTSD

Albert Leung, MD | VA San Diego Healthcare System | San Diego, CA
Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain

Byungkook Lim, PhD | UC 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 | UC San Diego | La Jolla, CA
Molecular and Circuit Effects of Psychedelic Drugs on the Central Nervous System

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

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

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

NIH/National Institute on Drug Abuse (NIDA) | CRO: The Emmes Company LLC | Rockville, MD
Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2) (CTN-0109)

NIH/National Institute on Drug Abuse (NIDA) | CRO: The Emmes Company | Rockville, MD
Placebo-Controlled Trial of Monthly Injectable Buprenorphine for Methamphetamine Use Disorder (CTN-0110)

Karthik Raman, PhD | Persist AI Formulations Corp with Psyence Group Inc. | Woodland, CA
Preclinical Investigation of the Feasibility and Design of PLG Encapsulated Psilocybin

Pierre Rivière, PhD | Peptide Logic | San Diego, CA
Anti-Fentanyl Monoclonal Antibodies

Jeffrey Sall, PhD, MD | UC San Francisco | San Francisco, CA
Effect of Cannabinoid Exposure on Brain Development and Behavior in a Postnatal Rat Model

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

Francesca Telese, MD | UC San Diego | La Jolla, CA
Neurobiological Mechanisms of Reward Behavior

Doris Tsao, PhD | UC Berkeley | Berkeley, CA
Panel Approved Research Project

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)

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

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

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

TABLE 2

RESEARCH STUDIES AMENDED IN 2023

Stephan Anagnostaras, PhD | UC San Diego | La Jolla, CA
Effects of Psychedelic Treatment on Mouse Models of Social Behavior, Addiction, Depression, Fear Memory, and Anxiety.

Kathleen Angkustsiri, MD | National Institute of Child Health and Human Development (NICHD) | UC Davis Mind Institute | Sacramento, CA
Evaluating Assessment and Medication Treatment of ADHD in Children with Down Syndrome

Melissa Bauman, PhD | UC Davis | Sacramento, CA
Neurodevelopmental Impact of Prenatal Cannabis Exposure

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

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)

Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Morrisville, NC
A Phase II, Multicenter, Randomized, 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, Multicenter, Randomized, Double-Blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants with Treatment-Resistant Depression (COMP 006)

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

David Hessl, PhD | UC Davis Mind Institute | Sacramento, CA
Randomized Controlled Trial of *Quillivant* in Intellectual Disability with ADHD

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA
Vaccine Research (Vaccines and Antidotes Against Drugs of Abuse)

Albert Leung, MD | VA San Diego Healthcare System | San Diego, CA
Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

Lykos Therapeutics (formerly MAPS Public Benefit Corporation [MAPS-PBC]) | San Jose, CA
A Multi-Site Open-Label Safety Extension Study of Manualized MDMA-Assisted Psychotherapy for the Treatment of Participants with Posttraumatic Stress Disorder (MAPPUSX)

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

Mind Medicine, Inc. | New York, NY
A Phase 2, Multi-Center, Randomized, Double-Blind, Parallel-Group, Dose-Finding Study to Assess the Effect of Four Doses of MM-120 for the Treatment of Anxiety Symptoms

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 (The RELIANCE-II 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)

Shannon Remick, MD | VA Loma Linda Healthcare System | Loma Linda, CA
Open-Label Phase 2 Study of MDMA-Assisted Psychotherapy in Veterans with Combat-Related, Refractory PTSD

Misty Stevens, PhD, MBA | 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

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)

Kay Tye, PhD | The Salk Institute for Biological Studies | La Jolla, CA
The Cellular Basis of Motivated Behaviors in Health and Disease: Assessment of Acute and Persistent Changes in Behavioral and Neural Correlates of Emotional Valence Processing Produced by Psilocybin

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)

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)

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

Joshua Woolley, MD, PhD | UC 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 | UC San Francisco with Filament Ventures | 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 | UC 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

TABLE 3

RESEARCH STUDIES CLOSED IN 2023

AnaBios Corporation, with Columbia University | San Diego, CA
CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl + Noribogaine

AnaBios Cororation., with Columbia University | San Diego, CA
CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl

AnaBios Corporation, with Columbia University | San Diego, CA
Evaluating the Effect of Ibogaine HCl on Human Dorsal Root Ganglion (DRGs) Neurons

Kathleen Angkustsiri, MD | National Institute of Child Health and Human Development (NICHD) | UC Davis Mind Institute | Sacramento, CA
Evaluating Assessment and Medication Treatment of ADHD in Children with Down Syndrome

CARI Health, Inc. | San Diego, CA
Interstitial Fluid Collection Validation Study

John Cashman, PhD | Human BioMolecular Research Institute | San Diego, CA
Molecular Evolution of Human Cocaine Catalysis

Melanie J. Cocco, PhD | UC Irvine | Irvine, CA
Creation of an NMR Library of H1-C13 Atomic Fingerprints of Pure Cannabis Components for the Analysis and Characterization of Cannabis and Cannabis Extracts

John S. Cowart, PhD | Seacoast Science, Inc. | Carlsbad, CA
Modular Biomimetic Polymers, Rationally Programmed to Detect a Panel of Cannabinoids

David P. Dumas, PhD | Amaratek | San Diego, CA
Low Temperature Plasma Mass Spectroscopy Identification of Aerosols

Empower Pharm Inc. | Ontario, Canada
A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study, Evaluating the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution in Subjects with Social Anxiety Disorder

Brook Henry, PhD | UC San Diego | San Diego, CA
Effect of Cannabis Administration and Endocannabinoids on HIV Neuropathic Pain Study - Phase 2

Edward Kisak, PhD | Ei Ventures, Inc. with Tioga Research | San Diego, CA
Research and Early Pharmaceutical Development of a Transdermal Dosage Form of Psilocybin

Sulggi Lee, MD, PhD | UC San Francisco | San Francisco, CA
Effect of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study

Lykos Therapeutics (Formerly MAPS Public Benefit Corporation [MAPS-PBC]) | San Jose, CA
MAPPUSX: A Multi-Site Open-Label Safety Extension Study of Manualized MDMA-Assisted Psychotherapy for the Treatment of Participants with Posttraumatic Stress Disorder (MAPPUSX)

Lykos Therapeutics (Formerly MAPS Public Benefit Corporation [MAPS-PBC]) | San Jose, CA
EAMP1 - An Intermediate Size Multi-Site Expanded Access Program for MDMA-Assisted Psychotherapy for Patients with Treatment-Resistant PTSD (MAPS EAMP1)

Lykos Therapeutics (Formerly MAPS Public Benefit Corporation [MAPS-PBC]) | San Jose, CA
A Phase 1, Open-Label, Multi-Site Study to Assess Psychological Effects of MDMA-Assisted Psychotherapy When Administered to Healthy Volunteers (MAPS MT2)

F. Kennedy McDaniel, PhD | Koniku, Inc. | Berkeley, CA
Development of a Device that Detects Controlled Substances

Mind Medicine, Inc. | New York, NY
A Phase 2, Multi-center, Randomized, Double-Blind, Parallel-Group, Dose-Finding Study to Assess the Effect of Four Doses of MM-120 for the Treatment of Anxiety Symptoms (MMED008)

National Institute on Drug Abuse (NIDA) | CRO: The Emmes Company, LLC | Rockville, MD
Placebo-Controlled Trial of Monthly Injectable Buprenorphine for Methamphetamine Use Disorder (CTN-0110)

Rudy M. Ortiz, PhD, FAPS, FAHA | UC Merced | Merced, CA
Potential CBD Benefits in Type 2 Diabetes

Karthik Raman, PhD | Persist AI Formulations Corp with Psyence Group Inc | Woodland, CA
Preclinical Investigation of the Feasibility and Design of PLG Encapsulated Psilocybin

Pierre Rivière, PhD | Peptide Logic | San Diego, CA
Anti-fentanyl Monoclonal Antibodies

Amanda Roberts, PhD | The Scripps Research Institute | La Jolla, CA
Effects of THC/alcohol Combinations in Utero on Adult Electrophysiology, Protein Levels, and Gene Expression

Christopher Savile, PhD | Epimeron USA, Inc. | Mountain View, CA
Development of a Cannabidiol (CBD) Producing Yeast Strain and Fermentation-Based Production Process

Stephen A. Spector, MD | UC San Diego | La Jolla, CA
Function of the Brain's Endocannabinoid System and Its Role in Neuro-AIDS and Neuro-Inflammation

Deepti Tanjore, PhD | Lawrence Berkeley National Lab | Emeryville, CA
Expression of Phytocannabinoids in Yeast: a High Yield Platform for Low Abundance Natural Products (Phase II)

Usona Institute | CRO: The Emmes Company | Rockville, MD
A Randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD)

Vertex Pharmaceuticals, Inc. | Boston, MA
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain after a Bunionectomy

Vertex Pharmaceuticals, Inc. | Boston, MA
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Dose Study Evaluating the Efficacy and Safety of VX-548 for Acute Pain after an Abdominoplasty

Moonbin Yim, PhD | ARK Diagnostics, Inc. | Fremont, CA
Research and Development of In-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing (1)

APPENDIX A

OPEN (THROUGH DECEMBER 31, 2023)
SCHEDULE I AND SCHEDULE II
ACADEMIC AND INDEPENDENT HUMAN RESEARCH STUDIES

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

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

Robin Carhart-Harris, PhD | UC San Francisco | San Francisco, CA
Multivariate Neural and Physiological Correlates of Psychedelic Sub-states:
A Within-Subjects, Healthy Volunteer Study With Experience-Sampling

Ziva Cooper, PhD | UC 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 | UC Lost 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 | UC 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 | UC 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 | UC Los Angeles | Los Angeles, CA
Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences between Men and Women

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

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

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

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

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

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

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

Jeremy Pettus, MD | UC San Diego | La Jolla, CA
The Effects of THC on Glucose Metabolism and Endothelial Function in Subjects with Type 2 Diabetes

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

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

Nathaniel M. Schuster, MD | UC 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

Michael A. Silver, PhD | UC Berkeley | Berkeley, CA
Investigating the Mechanisms of the Effects of Psilocybin on Visual Perception and Visual Representations in the Brain (BCSP01)

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)

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

Scott A. Wilke, MD, PhD | UC 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 | UC San Francisco with Filament Ventures | 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 | UC 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 | UC 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 | UC San Francisco | San Francisco, CA
Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease: A Pilot Study

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

APPENDIX B

OPEN (THROUGH DECEMBER 31, 2023)
CLINICAL DRUG TRIAL RESEARCH STUDIES

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 FT218 for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy (CLFT218-1901)

Albert Leung, MD | VA San Diego Healthcare System | San Diego, CA
Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

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

Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Morrisville, NC
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: Worldwide Clinical Trials | Morrisville, NC
A Phase III, Multicenter, Randomized, Double-Blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants with Treatment-Resistant Depression (COMP 006)

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) (REL-1017-302)

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) (REL-1017-310)

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)

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)

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)

APPENDIX C

OPEN (THROUGH DECEMBER 31, 2023)
CONTROLLED SUBSTANCE USE DISORDER TREATMENT
RESEARCH STUDIES

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

InterveXion Therapeutics | San Diego, CA
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 (OUTLAST)

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

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

NIH/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-0100)

NIH/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)

APPENDIX D

OPEN (THROUGH DECEMBER 31, 2023)
SCHEDULE I NON-HUMAN RESEARCH STUDIES

Hillel Adesnik, PhD | UC Berkeley | Berkeley, CA
Cellular and Circuit Mechanisms of Sensory Perception

Stephan Anagnostaras, PhD | UC San Diego | La Jolla, CA
Effects of Psychedelic Treatment on Mouse Models of Social Behavior, Addiction, Depression, Fear Memory, and Anxiety

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

Roberto C. Andresen Eguiluz, PhD | UC Merced | Merced, CA
Establishing the Role of Cannabinoids in Altering the Function of the Cardiovasculature

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

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 | UC Davis | Sacramento, CA
Neurodevelopmental Impact of Prenatal Cannabis Exposure

Ryan Baxter, PhD | UC Merced | Merced, CA
Cannabinoid Isolation, Purification, and Structure Diversification

Kevin Beier, PhD | UC Irvine | Irvine, CA
Effect of Adolescent THC Exposure on Future Substance Abuse

Ellen Breen, PhD | UC 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 | UC San Diego | La Jolla, CA
THC-Cannabinoid Receptor Pathway and CBD Activation of GPCRs on Cannabinoid Signaling Pathways in Head and Neck Squamous Cell Carcinoma (HNSCC)

Cesear Corona, PhD | Promega Corporation/ Usona Institute | San Luis Obispo, CA
Development of Tools and Technologies toward Understanding the Mechanism of Action, Safety, and Therapeutic Potential of Psychedelic Compounds

Cesear Corona, PhD | Promega Corporation/ Usona Institute | San Luis Obispo, CA
Synthesis and Biological Evaluation of Psychedelic Tryptamine Natural Products: Psilocybin, Psilocin, 5- MeO-DMT and N,N-DMT

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

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

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA
The Effect of DMT and 5-MeO DMT on Brain-Wide 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 Third-hand Exposures to Cannabis-Related Indoor Contaminants

Nicholas DiPatrizio, PhD | UC Riverside | Riverside, CA
Mechanism of Endocannabinoid Control of Feeding and Energy Balance

Davide Dulcis, PhD | UC 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

Christie Fowler, PhD | UC Irvine | Irvine, CA
Mechanisms of Drug Reinforcement

Neil Garg, PhD | UC Los Angeles | Los Angeles, CA
Optical and Electrochemical Detection of Tetrahydrocannabinol (THC) Towards a Functional Quantitative Breathalyzer

Olivier George, PhD | UC San Diego | La Jolla, CA
Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments

Olivier George, PhD | UC San Diego | La Jolla, CA
Animal Models of Addiction: Preliminary Studies of Vaporized THC Self-Administration in a Rat Model

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

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

Boris Dov Heifets, MD, PhD | Stanford University | Palo Alto, CA
Effects of Classical Hallucinogens on Learning and Memory

Judith Hellman, MD | UC San Francisco | San Francisco, CA
Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury

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

Gabriel Iftime, PhD | PARC, a Xerox Company | Palo Alto, CA
Roadside Drug Detection

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA
Vaccine Research (Vaccines and Antidotes against Drugs of Abuse)

Daniela Kaufer, PhD | UC Berkeley | Berkeley, CA
Unraveling Biological Mechanisms of Psychedelic Medicine Using Preclinical Models of PTSD

Mazen Kheirbek, PhD | UC San Francisco | San Francisco, CA
Testing Psilocybin as a Therapeutic in Mouse Models of Anxiety and Depression-Related Behavior.

Frank Kochinke, PhD | Mycrodose Therapeutics | San Diego, CA
Sustained Delivery of Psilocybin/Psilocin, LSD, MDMA, and DMT

Alexander Kutyrev, PhD | Aurora Fine Chemicals, LLC | San Diego, CA
Water Soluble Cannabinoids, Preparation and Use

Stephan Lammel, PhD | UC Berkeley | Berkeley, CA
Organization and Function of Neural Circuits in the Mammalian Brain

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

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

Byungkook Lim, PhD | UC 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 | UC San Diego | La Jolla, CA
Discovery and Reconstruction of Mescaline Biosynthesis

Loren Looger, PhD | UC San Diego | La Jolla, CA
Development of Fluorescent Sensors for Psychedelic Drugs

Loren Looger, PhD | UC 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 | UC Irvine | Irvine, CA
Neural Circuits Underlying Motivation and Addiction

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

Uri Manor, PhD | Salk Institute | 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 | UC 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

Alysson Muotri, PhD | UC San Diego | La Jolla, CA
The Impact of CBD/THC on Human Neurodevelopment

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

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)

David Olson, PhD | UC Davis | Davis, CA
Chemical Modulation of Neural Plasticity, Learning and Memory

Dilworth Parkinson, PhD | Lawrence Berkeley National Lab with Avadel | Emeryville, CA
X- ray Microtomography of Pharmaceuticals at the Advanced Light Source for Avadel

Jeanne Paz, PhD | J. David Gladstone Institute | San Francisco, CA
Role of Cannabidiol (CBD) in Inflammation in Generic and Acquired Epilepsy

Daniele Piomelli, PhD | UC Irvine | Irvine, CA
Antinociceptive Effects of Cannabinoids in Rodent Models: Cannabinoids in a Mouse Model of Sickle Cell Disease

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

Jeffrey Sall, PhD, MD | UC San Francisco | San Francisco, CA
Effect of Cannabinoid Exposure on Brain Development and Behavior in a Postnatal Rat Model

Suzaynn Schick, PhD | UC San Francisco with Biopharmaceutical Research Company | 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

Vikaas Sohal, MD, PhD | UC San Francisco | San Francisco, CA
Investigating Brain Circuits that Underlie Potentially Therapeutic Psychedelic Drugs

Matthew Springer, PhD | UC 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

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)

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

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

Francesca Telese, MD | UC San Diego | La Jolla, CA
Neurobiological Mechanisms of Reward Behavior

Doris Tsao, PhD | UC Berkeley | Berkeley, CA
Panel Approved Research Project

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)

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

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

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

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 | UC 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

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

Yi Zuo, PhD | UC Santa Cruz | Santa Cruz, CA
Chemical Modulation of Neural Circuits and Plasticity

APPENDIX E

2023 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 that 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 an 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 Officer, 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 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 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 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.

(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 variousmedical conditions who may be suitable participants in research on cannabis.

(3) Proposals shall contain provisions for a patient registry.

(4) Proposals shall contain provisions for an information system that is designed to record information about possible study participants, investigators, and clinicians, and deposit and analyze data that accrues as part of clinical trials.

(5) Proposals shall contain protocols suitable for research on cannabis, addressing patients diagnosed with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV), cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The proposal may also include research on other serious illnesses, provided that resources are available and medical information justifies the research.

(6) Proposals shall demonstrate the use of a specimen laboratory capable of housing plasma, urine, and other specimens necessary to study the concentration of cannabinoids in various tissues, as well as housing specimens for studies of toxic effects of cannabis.

(7) Proposals shall demonstrate the use of a laboratory capable of analyzing cannabis, provided to the program under this section, for purity and cannabinoid content and the capacity to detect contaminants.

(c) In order to ensure objectivity in evaluating proposals, the program shall use a peer review process that is modeled on the process used by the National Institutes of Health, and that guards against funding research that is biased in favor of or against particular outcomes. Peer reviewers shall be selected for their expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the applicants or the topic of an approach taken in the proposed research. Peer reviewers shall judge research proposals on several criteria, foremost among which shall be both of the following:

(1) The scientific merit of the research plan, including whether the research design and experimental procedures are potentially biased for or against a particular outcome.

(2) Researchers' expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the topic of, and the approach taken in, the proposed research.

(d) If the program is administered by the Regents of the University of California, any grant research proposals approved by the program shall also require review and approval by the research advisory panel.

(e) It is the intent of the Legislature that the program be established as follows:

(1) The program shall be located at one or more University of California campuses that have a core of faculty experienced in organizing multidisciplinary scientific endeavors and, in particular, strong experience in clinical trials involving psychopharmacologic agents. The campuses at which research under the auspices of the program is to take place shall accommodate the administrative offices, including the director of the program, as well as a data management unit, and facilities for detection and analysis of various naturally occurring and synthetic cannabinoids, as well as storage of specimens.

(2) When awarding grants under this section, the program shall utilize principles and parameters of the other well-tested statewide research programs administered by the University of California, modeled after programs administered by the National Institutes of Health, including peer review evaluation of the scientific merit of applications.

(3) The scientific and clinical operations of the program shall occur partly at University of California campuses and partly at other postsecondary institutions that have clinicians or scientists with expertise to conduct the required studies. Criteria for selection of research locations shall include the elements listed in subdivision (b) and, additionally, shall give particular weight to the organizational plan, leadership qualities of the program director, and plans to involve investigators and patient populations from multiple sites.

(4) The funds received by the program shall be allocated to various research studies in accordance with a scientific plan developed by the Scientific Advisory Council. As the first wave of studies is completed, it is anticipated that the program will receive requests for funding of additional studies. These requests shall be reviewed by the Scientific Advisory Council.

(5) The size, scope, and number of studies funded shall be commensurate with the amount of appropriated and available program funding.

(f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.

(g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, cannabis. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

(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.

(1) To enhance understanding of the efficacy and adverse effects of cannabis as a pharmacological agent, the program shall conduct focused controlled clinical trials on the usefulness of cannabis in patients diagnosed with AIDS or HIV, cancer,

glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The program may add research on other serious illnesses, provided that resources are available and medical information justifies the research. The studies shall focus on comparisons of both the efficacy and safety of methods of administering the drug to patients, including inhalational, tinctural, and oral, evaluate possible uses of cannabis as a primary or adjunctive treatment, and develop further information on optimal dosage, timing, mode of administration, and variations in the effects of different cannabinoids and varieties of cannabis or synthetic compounds that simulate the effects of naturally occurring cannabinoids. The studies may also focus on examining testing methods for detecting harmful contaminants in cannabis, including, but not limited to, mold, bacteria, and mycotoxins that could cause harm to patients.

(2) The program shall examine the safety of cannabis in patients with various medical disorders, including the interaction of cannabis with other drugs, relative safety of inhalation versus oral forms, and the effects on mental function in medically ill persons.

(3) The program shall be limited to providing for objective scientific research to ascertain the efficacy and safety of cannabis as part of medical treatment, and should not be construed as encouraging or sanctioning the social or recreational use of cannabis.

(m)(1) Subject to paragraph (2), the program shall, prior to approving proposals, seek to obtain research protocol guidelines from the National Institutes of Health and shall, if the National Institutes of Health issues research protocol guidelines, comply with those guidelines.

(2) If, after a reasonable period of time of not less than six months and not more than a year has elapsed from the date the program seeks to obtain guidelines pursuant to paragraph (1), no guidelines have been approved, the program may proceed using the research protocol guidelines it develops.

(n) In order to maximize the scope and size of the cannabis studies, the program may do any of the following:

(1) Solicit, apply for, and accept funds from foundations, private individuals, and all other funding sources that can be used to expand the scope or timeframe of the cannabis studies that are authorized under this section. The program shall not expend more than 5 percent of its General Fund allocation in efforts to obtain money from outside sources.

(2) Include within the scope of the cannabis studies other cannabis research projects that are independently funded and that meet the requirements set forth in subdivisions
(a) to (c), inclusive. In no case shall the program accept funds that are offered with any conditions other than that the funds be used to study the efficacy and safety of cannabis as part of medical treatment.

(o) (1) Within six months of the effective date of this section, the program shall report to the Legislature, the Governor, and the Attorney General on the progress of the cannabis studies.

(2) Thereafter, the program shall issue a report to the Legislature every 24 months detailing the progress of the studies. The interim reports required under this paragraph shall include, but not be limited to, data on all of the following:

(A) The names and number of diseases or conditions under study.
(B) The number of patients enrolled in each study, by disease.
(C) Any scientifically valid preliminary findings.

(p) If the Regents of the University of California implement this section, the President of the University of California, or the president's designee, shall appoint a multidisciplinary Scientific Advisory Council, not to exceed 15 members, to provide policy guidance in the creation and implementation of the program. Members shall be chosen on the basis of scientific expertise. Members of the council shall serve on a voluntary basis, with reimbursement for expenses incurred in the course of their participation. The members shall be reimbursed for travel and other necessary expenses incurred in their performance of the duties of the council.
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(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 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

(6) regulations and to minimize any negative impact that the programs may have onthe communities in which they are located.

(7) In its discretion, to approve local agencies or bodies to assist it in carrying out this chapter provided that the department may not delegate responsibility for inspection or any other licensure activity without prior and specific statutory approval. However, the department shall evaluate recommendations made by county alcohol and drug program administrators regarding licensing activity in their respective counties.

(8) 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 exceed fees collected during a fiscal year.

(d) Notwithstanding any provision of this code or regulations to the contrary, the department shall have sole responsibility and authority for determining if a state narcotic treatment program license shall be granted and for administratively establishing the maximum treatment capacity of a license. However, the department shall not increase the capacity of a program unless it determines that the licensee is operating in full compliance with applicable laws and regulations.

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

(a) (1) Each narcotic treatment program authorized to use narcotic replacement therapy in this state, except narcotic treatment research programs approved by the Research Advisory Panel, shall be licensed by the department.

(2) Each narcotic treatment program, other than a program owned and operated by the state, county, city, or city and county, shall, upon application for licensure and for renewal of a license, pay an annual license fee to the department. July 1 shall be the annual license renewal date.

(3) The department shall set the licensing fee at a level sufficient to cover all departmental costs associated with licensing incurred by the department, but the fee shall not, except as specified in this section, increase at a rate greater than the Consumer Price Index. The fees shall include the department's share of pro rata charges for the expenses of state government. The fee may be paid quarterly in arrears as determined by the department. Fees paid quarterly in arrears shall be due and payable on the last day of each quarter except for the fourth quarter for which payment shall be due and payable no later than May 31. A failure of a program to pay renewal license fees by the due date shall give rise to a civil penalty of one hundred dollars ($100) a day for each day after the due date. Second and subsequent inspection visits to narcotic treatment programs that are operating in noncompliance with the applicable laws and regulations shall be charged a rate of one-half the program's annual license fee or one thousand dollars ($1,000), whichever is less, for each visit.

(4) Licensing shall be contingent upon determination by the department that the program is in compliance with applicable laws and regulations and upon payment of the licensing fee. A license shall not be transferable.

(5) (A) As used in this chapter, "quarter" means July, August, and September; October, November, and December; January, February, and March; and April, May, and June.

(B) As used in this chapter, "license" means a basic permit to operate a narcotic treatment program. The license shall be issued exclusively by the department and operated in accordance with a patient capacity that shall be specified, approved, and monitored solely by the department.

(b) Each narcotic treatment program, other than a program owned and operated by the state, county, city, or city and county, shall be charged an application fee that shall be at a level sufficient to cover all departmental costs incurred by the department in processing either an application for a new program license, or an application for an existing program that has moved to a new location.

(c) Any licensee that increases fees to the patient, in response to increases in licensure fees required by the department, shall first provide written disclosure to the patient of that amount of the patient fee increase that is attributable to the increase in the licensure fee. This provision shall not be construed to limit patient fee increases imposed by the licensee upon any other basis.

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

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in Section 24175, this list shall include, but not be limited to the subject's right to:

(a) Be informed of the nature and purpose of the experiment.

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

(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 non- technical 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.

(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.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

ADDENDUM

2023 RESEARCH STUDIES APPROVED IN 2024

ACADEMIC AND INDEPENDENT HUMAN RESEARCH STUDIES

Ausaf Bari, MD, PhD | UC 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 | UC Los Angeles | Los Angeles, CA
Tolerability of MDMA in Schizophrenia

Robin Carhart-Harris, PhD | UC 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 | UC 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 | UC Los Angeles | Los Angeles, CA
Sex- and Age-Dependent Effects of Smoked and Oral Delta-9-THC

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

Marissa Raymond-Flesch, MD, MPH | UC San Francisco | San Francisco, CA
Study of Psilocybin for the Treatment of Anorexia Nervosa in Young Adults

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

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

CLINICAL DRUG TRIAL RESEARCH STUDIES

Beckley Psytech Ltd. | Nottingham, UK
A Quadruple Masked, Dose-Finding Study to Evaluate the Efficacy and Safety of Intranasal BPL-003 in Patients with Treatment-Resistant Depression.
(BPL-003-201 (CORE)

Charles Grob, MD | Harbor UCLA Medical Center | 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)

Relmada Therapeutics, Inc. | Coral Gables, FL
A Randomized, Double-Blind Placebo-Controlled Trial of REL-1017 as an Adjunctive Treatment for Major Depressive Disorder (REL-1017-304, RELIGHT)

SUBSTANCE USE DISORDER TREATMENT RESEARCH STUDIES

CARI Health, Inc | San Diego, CA
Assessing Methadone Dose Taken Using Electrochemistry

Ziva Cooper, PhD | UC Los Angeles | Los Angeles, CA
Safety Profile of 25 mg Psilocybin in Individuals with Cocaine Use Disorder

David Fiellin, MD | Yale/ National Institute on Drug Abuse (NIDA) | New Haven, CT
Office-Based Methadone versus Buprenorphine to Address Retention in Medication for Opioid Use Disorder Treatment-A Randomized Pragmatic Hybrid Effectiveness/Implementation Trial (NIDA CTN-0131)

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

NON-HUMAN RESEARCH STUDIES

Kevin Beier, PhD | UC Irvine | Irvine, CA
Reversing Maladaptive Plasticity Using Psilocybin

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

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

David E. Krantz, MD, PhD | UC Los Angeles | Los Angeles, CA
Serotonergic signaling in Drosophila

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

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, MD, | UC Irvine | Irvine, CA
A Translational Study on the Short- and Long-term Effects of High Dose Delta-9-tetrahydrocannabinol (THC)

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

AMENDED STUDIES

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

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

Frank Kochinke, PhD | LyfeChng| San Diego, CA
Sustained Delivery of Psilocybin/Psilocin, LSD, MDMA, and DMT with Synthesis of APIs

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)

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

Joshua Woolley, MD, PhD | UC 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