

2  
0  
2  
2

# Research Advisory Panel of California



**RAPC**  
RESEARCH ADVISORY  
PANEL OF CALIFORNIA

**52nd 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>

E-mail contact: [RAPC@doj.ca.gov](mailto:RAPC@doj.ca.gov)

This report represents a consensus among Panel members acting as individual experts.

It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

## TABLE OF CONTENTS

Research Advisory Panel of California.....	4
LIST OF 2022 PANEL MEMBERS.....	5
SUMMARY OF 2022 PANEL ACTIVITIES.....	6
SELECTED RESEARCH FINDINGS .....	7
TABLE 1 - Research studies approved in 2022 (new).....	13
TABLE 2 – Research Studies approved in 2022 (amended) .....	16
TABLE 3 - Research studies closed in 2022.....	18
<b>APPENDICES</b>	
<b>Appendix A - Currently Open Schedule I and II</b>	
Academic and Independent Human Research Studies.....	21
<b>Appendix B - Currently Open Schedule I and II</b>	
Multi-Center Clinical Drug Trial Research Studies.....	24
<b>Appendix C - Currently Open Research Studies</b>	
Treatment of Substance Use Disorder Research Studies .....	26
<b>Appendix D - Currently Open Schedule I</b>	
Non-Human Research Studies.....	27
<b>Appendix E - Pertinent Sections - California Health and Safety Code</b>	
Section 11213 - Persons and research using controlled substances.....	34
Section 11392 - Authorized acquisition for use in bona fide research, instruction, or analysis .....	34
Section 11480 and 11481 - Research Advisory Panel.....	34-35
Section 11603 and 11604 - Attorney General .....	35-36
Section 11362.9 - Cannabis Research Program .....	36
Section 11839.3 - Duties of Department .....	40
Section 11839.7 - License required; Fee; Compliance with laws and regulations; Disclosure of fee increases.....	42
Section 24172 - Experimental subject’s bill of rights.....	43
Section 24173 - Informed consent.....	44

## **RESEARCH ADVISORY PANEL OF CALIFORNIA**

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 to be reviewed and authorized by the Research Advisory Panel of California (RAPC) in the Attorney General's Office.

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 Panel Members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

## **2022 PANEL MEMBERS**

### **RESEARCH ADVISORY PANEL OF CALIFORNIA**

The Research Advisory Panel of California (RAPC) consists of the Panel Chair and the Panel members. RAPC also retains one staff member, the Executive Officer.

#### **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

#### **Angie Chen, MD, FACP**

Clinical Associate Professor, Stanford University School of Medicine  
Appointed by Stanford University  
(Through March 27, 2022)

#### **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, California Dept. of Health Care Services  
Appointed by the California Department of Public Health

#### **Boris Heifets, MD, PhD**

Assistant Professor, Stanford University School of Medicine  
Appointed by Stanford University  
(Since May 24, 2022)

#### **Andrew S. Kayser, MD, PhD**

Professor of Neurology, UCSF School of Medicine  
Appointed by the University of California

#### **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  
Appointed by the California State Governor

#### **EXECUTIVE OFFICER**

#### **Tanveer Khan, PharmD**

RAPC Executive Officer  
Appointed by the California State Attorney General

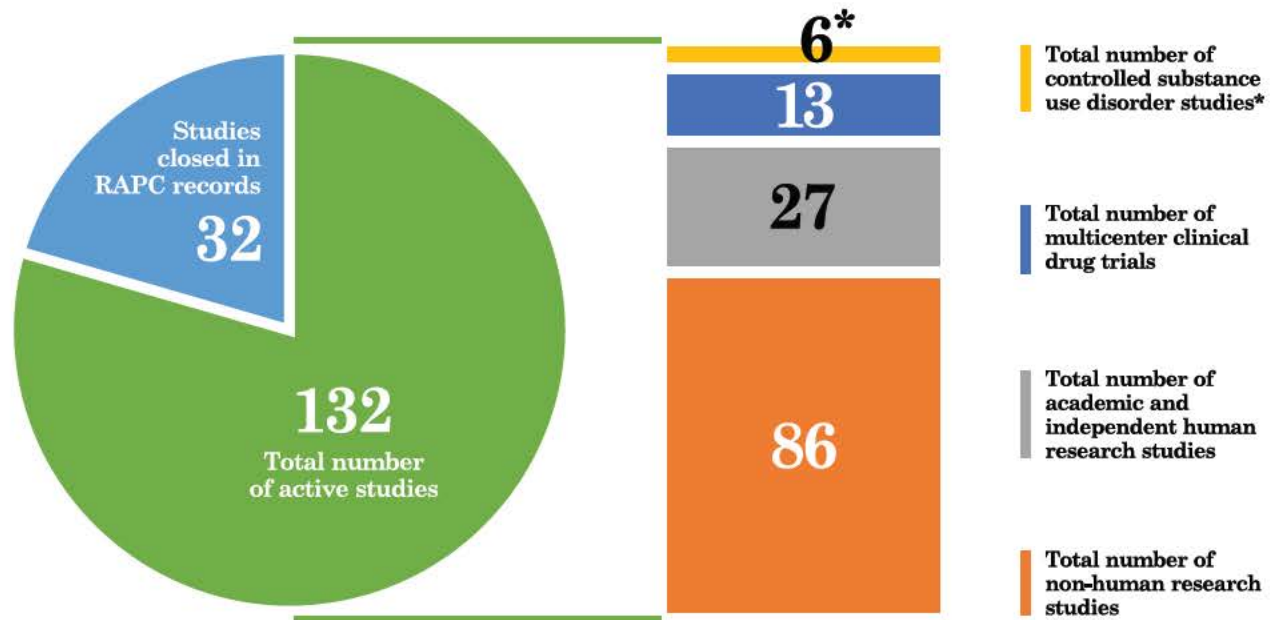
## SUMMARY OF 2022 PANEL ACTIVITIES

During the 2022 calendar year (Jan 1 – Dec 31), the Research Advisory Panel of California (RAPC) reviewed 52 new applications for research, and finalized two applications from 2021. Of these 54 applications, RAPC approved 36 new studies and three research applications were either not approved or withdrew their applications. The remaining 15 applications were pending finalization at the close of the 2022 calendar year. RAPC also approved 18 substantially amended studies during this reporting period.

Among the new studies approved by RAPC, six studies are academic or independent human research studies, four studies are multi-center clinical drug trial research, two studies are on the treatment of controlled substance use disorder, and 24 studies are non-human research projects. Thirty-two research studies were completed or terminated in 2022 and their files were closed in RAPC’s records.

Table 1 illustrates the breakdown of new studies approved by RAPC in 2022. Table 2 shows amended studies approved by RAPC. Table 3 represents studies closed in RAPC records.

By the end of 2022, RAPC was monitoring 132 active research projects. 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, significant adverse event reports, and site visits. No site visits were performed between January 1, 2022 and December 31, 2022, due to the COVID pandemic. Approval may be withdrawn if the study activities deviate significantly from the approved protocol.

\*(Please note that a study is placed in only one category. The total number of studies that involve substance use disorder research is understated on this chart for purposes of computing research totals.)

## SELECTED RESEARCH FINDINGS

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

**Dr. Nathaniel Schuster, MD** and colleagues at the University of California (UC) San Diego Center for Pain Medicine are conducting a human research study entitled “Efficacy of Inhaled Cannabis Versus Placebo for the Acute Treatment of Migraine: A Randomized, Double-Blind, Placebo-Controlled, Crossover Trial.” Dr. Schuster has provided the following abstract of this research study:

Despite more migraine treatment than ever before, many people with migraine may still have incomplete results or be resistant to these therapies. These resistant patients, up to 50% of migraineurs, may be self-treating with non-proven remedies, including cannabis. Cannabis has a long history of use as a botanical medicine, with specific evidence as a migraine treatment, purported to have benefit for both prevention of migraine and acute treatment. Sir William Osler, considered by many to be the father of modern medicine, wrote in his 1916 textbook that cannabis was “probably the most satisfactory remedy” for migraine. Preclinical research provides several possible mechanisms by which cannabis may work, including inhibition of the trigeminovascular system, reducing serotonin release from platelets, direct effects on serotonin receptors, inhibition of cortical spreading depression or addressing a purported endocannabinoid deficiency in people with migraine. However, there has never been a formal clinical trial of cannabis for acute (abortive) treatment of migraine attacks until now. In our first study (NCT04360044), volunteers are treating four distinct migraine attacks (seven days apart), each with one of three cannabis potencies: 5% THC, mix of 5% THC and 12% CBD and 12% CBD plus a placebo cannabis (all cannabinoids extracted from the plant material). The primary endpoint is headache pain relief at 2 hours and the key secondary endpoints are freedom from headache pain and most bothersome symptom at a 2-hour time point, post inhalation of cannabis, using a vaporization device (Mighty; Storz & Bickel). This clinical trial has completed enrollment (N=92) and statistical analysis of the results is ongoing. We have already begun a dose-ranging extension study (NCT05427630), Inhaled cannabis versus placebo for the acute treatment of migraine: a pilot, randomized, double-blind, placebo-controlled, crossover, dose-ranging trial where 20 of the participants from the first study (NCT04360044) are treating four additional acute migraines inhaling vaporized cannabis of 2.5%, 5% or 10% THC content and placebo.

**Dr. Timothy Furnish, MD**, from the Center for Pain Medicine at UC San Diego Medical Center is conducting a human research project entitled “Behavioral and Neural Mechanisms Supporting Psilocybin Assisted Therapy for Phantom Limb Pain.” Dr. Furnish provides the following abstract of this research project:

Approximately 50–80% of amputees experience intractable phantom limb pain which is a debilitating pain condition caused by a complex interplay between sensory, cognitive, and affective neural processes. Converging lines of evidence suggest that classical/serotonergic psychedelics including lysergic acid diethylamide (LSD) and psilocybin can reduce phantom limb pain. For example, early studies demonstrated relief of phantom limb pain following treatment with LSD and a recent case study found similar results in an individual with phantom limb

pain who self-administered psilocybin. A new wave of clinical trials has established classical psychedelics as effective treatments for health conditions such as depression, and substance abuse problems, and relief of pain and psychological distress in cancer patients following treatment with LSD has been observed. However, the neural mechanisms related to psychedelic induced pain relief remain unclear.

Psychedelics have been proposed to “reset” neurofunctional connections in the brain which have been found to be aberrant in phantom limb pain. Moreover, serotonergic psychedelics have been found to decrease sensorimotor network connectivity and overrepresentation of the phantom in sensorimotor areas corresponds positively with pain in phantom limb patients.

Despite these observations, no study to date has investigated the effect of psilocybin on pain experience and the underlying neural mechanisms in phantom limb pain patients. To bridge these gaps, our double-blind, randomized, placebo-controlled studies will employ functional magnetic resonance imaging (fMRI), psychophysical (i.e., psychological evaluation of physical processes) pain testing, and a battery of surveys investigating pain-health outcomes, prior to and following administration of psilocybin in phantom limb patients.

**Dr. Matthew Springer, PhD** and colleagues from UC San Francisco Division of Cardiology are conducting non-human research entitled “Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers.” Dr. Springer provides the following abstract of this research study:

Despite a wealth of information about the adverse health effects of tobacco smoke collected over many decades of study, far less is known about potential adverse effects of marijuana smoke or leaf vaporizer use. Marijuana smoke contains most of the same thousands of chemicals that tobacco smoke contains, and inhalation of any kind of smoke involves exposure to many toxic compounds. We have shown that in a rat model of vascular function that mimics the human situation, even a brief exposure (as little as one minute) to secondhand smoke from tobacco or marijuana at real world relevant levels impairs the proper functioning of blood vessels (vascular endothelial function), and similar health effects are observed after the rat equivalent of actively smoking a single tobacco or marijuana cigarette. Marijuana leaf vaporizer aerosol results in similar impairment. More recently, we have observed that daily exposures of rats to marijuana smoke (one smoking session per day) interferes with cardiac function, increases cardiac scarring (fibrosis), and increases the susceptibility to arrhythmias (heart rhythm disturbances). We have also shown that both smoke and vaporizer aerosol from research marijuana from different sources (including one condition that closely mimics real-world marijuana used by the public), with a range of cannabinoid profiles and drying regimens, impairs endothelial function in rats similarly. This indicates that results of such experiments should not be discounted due to being done with “research marijuana.” Such information is important for regulators, lawmakers, and the public, because the awareness that marijuana is not benign and can have at least some of the harmful effects of tobacco will help people to make wise decisions about their own personal health behaviors and will help to protect others from being involuntarily exposed to harmful smoke.



**Dr. Mohammed A. Bari, MD** and colleagues at CARI Health, Inc. have conducted a substance use disorder research study entitled “Interstitial Fluid Collection Validation Study.” CARI Health, Inc. has provided the following summary of this study:

- A. This pilot study was an exploratory feasibility study that aimed to determine if common medications for opioid use disorder (OUD; i.e., methadone and buprenorphine) and their metabolites (i.e., norbuprenorphine [a metabolite of buprenorphine], buprenorphine-3-glucuronide [B3G; a metabolite in buprenorphine], ethylidene dimethyl diphenyl pyrrolidine [EDDP, the main metabolite for methadone]), can be detected in dermal interstitial fluid (ISF). The objective of the study was to collect microliter volumes of ISF from the surface of the skin from patients with a prescription for each these medications (methadone n = 10; buprenorphine n = 2; and controls (n=3) by using a minimally invasive microneedle array in conjunction with a standard vacuum pump. Since this was groundbreaking research, it was not clear what to expect, but it was anticipated that levels of these medications and their metabolites would be detected and quantitated in these samples by using standard instrumental chemical analysis for comparison to blood samples.
- B. The study had three aims:
- Aim 1: To detect and quantitate methadone in ISF collected from the surface of the skin using a minimally invasive microneedle array and suction.
  - Aim 2: To detect and quantitate buprenorphine in ISF collected from the surface of the skin using a minimally invasive microneedle array and suction (1).
  - Aim 3: To establish correspondence between detected medication levels in ISF and blood.
- C. Findings
1. All 20 ISF samples extracted from 10 methadone patients were positive for methadone.
  2. Buprenorphine could not be conclusively detected in the two (2) buprenorphine patients.
  3. All three (3) ISF samples from control subjects did not show detectable levels of methadone or buprenorphine.
  4. Eight (8) ISF samples from four (4) methadone patients were excluded because they tested positive for illicit substances that may confound correlation studies.
  5. 12 ISF samples from six (6) methadone patients met the inclusion criteria.
  6. For each of the six (6) patients that met the inclusion criteria the methadone levels in the ISF were higher after they ingested the dose compared to before.
  7. Patients that met the inclusion criteria had higher methadone levels three hours after ingestion compared to immediately before ingestion.
  8. Methadone levels in ISF correlated strongly with methadone levels in plasma, both before and after ingestion. The Pearson coefficient for all 10 samples (excluding subject taking gabapentin) was 0.806 with a p value of 0.005.
  9. Methadone metabolite EDDP was present in ISF, and its concentrations correlated with those in plasma. The Pearson coefficient of all 10 samples (excluding subject taking gabapentin) was 0.837 with a p value of 0.003.

#### D. Conclusions

The primary goal of this study was to detect methadone in ISF at levels that would allow an electrochemical dermal sensor to monitor its concentration. The findings of 5 times higher concentrations of methadone in the ISF compared to plasma supports the conclusion that this goal is feasible in patients taking at least 60 mg of methadone per day.

The secondary goal of this study was to determine the technical feasibility of monitoring buprenorphine with the same electrochemical dermal sensor. Unfortunately, the data suggests that this will not be feasible with the current expected level of sensitivity of the planned sensor.

The third aim of the study was successfully demonstrated. There is a strong correlation of methadone levels in the ISF and blood. Therefore, ISF can be used to follow the pharmacokinetics of methadone as a surrogate to monitoring blood levels. This new fact means that continuous remote monitoring of medication compliance and objective data based, personalized dosimetry using ISF are technically feasible.

**Avadel Pharmaceuticals with CRO, Advanced Clinical**, are conducting a clinical human drug trial entitled “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).” Avadel and Advanced Clinical provide the following summary of this trial:

Sodium oxybate has been FDA approved for the treatment of narcolepsy since 2002 as an immediate-release oral solution requiring two doses, the first dose taken at bedtime and a second dose required 2.5 to 4 hours later. FT218 is an investigational, extended-release form of sodium oxybate, packaged as pre-measured, unit-of-use single nightly dose packs.

The primary aim of this study is to evaluate long-term safety and tolerability of FT218. The first patient was enrolled in July 2020; enrollment closed in June 2022. A total of 184 participants enrolled and 180 have taken at least one dose of FT218. At the last interim data cut (November 7, 2022), adverse reactions have been consistent with the known safety/tolerability of sodium oxybate (>5%: nausea, headache, somnolence, dizziness, enuresis, somnambulism). Thus far, 5.6% of the participants who have received at least one dose have withdrawn due to adverse reactions.

A secondary aim of the study is to evaluate switching from twice-nightly, immediate-release sodium oxybate (Xyrem® and mixed-salt oxybates [Xywav®; calcium/magnesium/potassium/sodium oxybates]). A majority of the 130 participants who have switched from the twice-nightly formulations have maintained a similar total nightly dose. Among switch participants, 93% have reported a preference for the once-nightly dosing regimen.

Participants also include those that completed the pivotal, randomized, placebo-controlled clinical trial (REST-ON; Kushida et al. SLEEP 2022), but have not yet started a commercially

available oxybate. In 2021, the inclusion criteria was expanded to sodium oxybate-naïve participants. For both of these groups, efficacy is evaluated via the Epworth Sleepiness Scale, Clinical Global Impression of Improvement, Patient Global Impression of Improvement, and sleep and symptom diary.

FT218 (LUMRYZ™) received tentative approval from FDA in July 2022. The study is currently planned for the last patient last visit (LPLV) in October 2023. (Xyrem and Xywav are registered trademarks of Jazz Pharmaceuticals.)

**Dr. Yi Tang, PhD** and colleagues from UC Los Angeles Department of Chemical and Biomolecular Engineering are conducting non-human research entitled “Synthetic Biology Approaches to Cannabinoid Diversification and Production.” Dr. Tang provides the following abstract of this project:

A non-plant biosynthetic pathway that produces olivetolic acid (OA), the first key intermediate in the cannabinoid biosynthetic pathway, has been elucidated. The novel platform utilizes a set of tandem polyketide synthases that can produce OA and its analogs at high titers using the model organism *Aspergillus nidulans*. This platform represents a new strategy to produce these cannabinoid precursors in microbes without relying on plant enzymes, leading to higher titers and a flexible engineering pathway to access rare or unnatural cannabinoids. The ability to produce cannabinoids without relying on plant production can be groundbreaking for cannabinoid-based medicines (CBMs), which have shown promise as antidepressants, analgesics, anticonvulsants, antiemetics and in treatment of cancer cells. When compared with the plant pathway production of OA, this biosynthetic pathway provides increased production, diversity, and selectivity. This platform has the potential to not only produce common cannabinoids like Delta-9-tetrahydrocannabinol (Delta-9-THC) and cannabidiol (CBD) but also rare and potentially more potent cannabinoids due to the diversity of analog products produced.

**Dr. Brook Henry, PhD** from the Department of Psychiatry at UC San Diego is conducting a human research project entitled “Cannabis Effects on Antiretroviral Therapy Pharmacokinetics and Neurotoxicity.” Dr. Henry provides the following summary of this project:

Individuals living with HIV frequently use cannabis, but it is not clear how the drug affects the antiretroviral therapy (ART) that treats the disease. Cannabis can inhibit the activity of enzymes that eliminate ART from the body, which may increase ART concentrations. Cannabis may also affect the ability of ART to enter the brain, which could have both beneficial (e.g., better HIV control) and detrimental (e.g., toxicity) consequences. In addition, the effects of cannabis may depend on factors such as quantity and the route of use (smoked vs. vaporized). This study will address several important questions:

- 1) Does cannabis affect concentrations of ART in blood and the brain?
- 2) Does the drug impact viral control and immune function such as CD4 count?
- 3) Does cannabis influence the effects of ART on mood, cognitive function, and inflammation?

Our project consists of two phases. Phase 1 is an observational study in which 120 people will be assessed at one visit to evaluate the effects of chronic cannabis on ART. In Phase 2, we will administer cannabis or placebo to 40 participants during three separate visits to examine acute effects of THC and CBD on ART. To date, we have screened more than 50 participants for the study. We have collected data for Phase 1 (observational visits) and Phase 2 (cannabis administration).

## TABLE 1

### RESEARCH STUDIES APPROVED IN 2022

**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

**Nick Andrews, PhD | The Salk Institute | La Jolla, CA**

Effect of the Psychedelic Class of Pharmaceuticals in Preclinical Models of Chronic Pain

**Mohammed A. Bari, MD | Cari Health, Inc | San Diego, CA**

Interstitial Fluid Collection Validation Study

**Kevin Beier, PhD | UC Irvine | Irvine, CA**

Effect of Adolescent THC Exposure on Future Substance Abuse

**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

**Nicholas V. Cozzi, PhD | Alexander Shulgin Research Institute (ASRI) | Berkeley, CA**

Synthesis and Structure-Activity Relationships of Psychoactive Drugs Acting on Biogenic Amine Systems

**Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Cheshire, United Kingdom**

Efficacy and Safety of COMP360 Psilocybin Therapy in Anorexia Nervosa: A Proof-Of-Concept Study

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

The Effect of DMT and 5-MeO DMT on Brain-Wide Activity and Behavior

**David P. Dumas, PhD | Amaratek | San Diego, CA**

Low Temperature Plasma Mass Spectroscopy Identification of Aerosols

**EmpowerPharm, 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

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

Effects of Psilocybin on Embryonic Development

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

**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

**Jazz Pharmaceuticals/ (formerly Greenwich Biosciences) | Dublin, Ireland**  
A Double-blind, Randomized, Placebo-controlled, Parallel-group Trial of the Efficacy and Safety of Nabiximols Oromucosal Spray as Add-on Therapy in Patients with Spasticity Due to Multiple Sclerosis

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

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

**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

**Uri Manor, PhD | The Salk Institute | La Jolla, CA**  
Therapeutic Potential and Mechanism of Psychoplastogen Compounds

**Lisa A. Miller, PhD | UC Davis | Davis, CA**  
Novel Use of Human iPSC Derived Airway Progenitor Cells to Measure E-Cigarette Toxicity

**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

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

**Svetlana Nikoulina, PhD | Pharmaron | 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)

**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

**Daniele Piomelli, PhD | UC Irvine | Irvine, CA**

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

**Suzaynn Schick, PhD | UC San Francisco | San Francisco, CA**

Measuring Environmental Tobacco and Cannabis: Pollutants and Exposures

**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, Cross-over, Dose-Ranging 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

**Vikaas Sohal, MD, PhD | UC San Francisco | San Francisco, CA**

Investigating Brain Circuits that Underlie Potentially Therapeutic Psychedelic Drugs

**Yi Tang, PhD | UC Los Angeles | Los Angeles, CA**

Synthetic Biology Approaches to Cannabinoid Diversification and Production

**Kaye Tye, PhD | The 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

**Marc Weintraub, PhD | UC Los Angeles | Los Angeles, CA**

Psilocybin - Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

**Jennifer Wenzel, PhD | University of San Diego | San Diego, CA**

The Effects of Adolescent Cannabinoid Exposure on Cocaine Reward and Aversion

**Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA**

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

**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

## TABLE 2

### RESEARCH STUDIES WITH AMENDMENTS APPROVED IN 2022

**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)

**Melissa Bauman, PhD | UC Davis | Sacramento, CA**

Neurodevelopmental Impact of Prenatal Cannabis Exposure

**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

**Adam Halberstadt, PhD | UC San Diego | La Jolla, CA**

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

**Compass Pathfinder Limited | CRO: Worldwide Clinical Trials |  
Cheshire, United Kingdom**

Efficacy and Safety of COMP360 Psilocybin Therapy in Anorexia Nervosa: A Proof-Of-Concept Study

**Edward Kisak, PhD | Tioga Research | San Diego, CA**

Research and Early Pharmaceutical Development of a Transdermal Dosage Form of Psilocybin

**Stephan Lammel, PhD | UC Berkeley | Berkeley, CA**

Organization and Function of Neural Circuits in the Mammalian Brain

**Stephen Mahler, PhD | UC Irvine | Irvine, CA**

Neural Circuits Underlying Motivation and Addiction

**MAPS Public Benefit Corporation (MAPS-PBC) | San Jose, CA**

A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder of Moderate or Greater Severity (MAPP2)

**MAPS Public Benefit Corporation (MAPS-PBC) | San Jose, CA**

An Intermediate size Multi-Site Expanded Access Program for MDMA-Assisted Psychotherapy for Patients with Treatment-Resistant PTSD (EAMP1)



**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)

**Rudy M. Ortiz, PhD, FAPS, FAHA | UC Merced | Merced, CA**

Potential CBD Benefits in Type 2 Diabetes

**Ivan Soltesz, PhD | Stanford University | Stanford, CA**

Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy

**Vertex Pharmaceuticals, Inc. | CRO: ICON Strategic Solutions | 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. | CRO: ICON Strategic Solutions | 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

**Marc Weintraub, PhD | UC San Diego | Los Angeles, CA**

Psilocybin - Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

**Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA**

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

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

Human iPSCs for Elucidating Cardiovascular Risks of Cannabis

**TABLE 3**  
**RESEARCH STUDIES**  
**CLOSED IN 2022**

**Richard Baldwin, PhD | Fortis Life Sciences (Formerly nanoComposix) | San Diego, CA**

Biosensor for the Detection of Synthetic Cannabinoids

**Nelson Barton, PhD | Genomatica | San Diego, CA**

Microbial Processes for the Manufacture of Specialty Chemicals

**Brian Brandley, MBA, PhD | Biopharmaceutical Research Company (BRC) | Castroville, CA**

Characterization of Model Systems for Longevity Studies, Genetics and Neuroscience; Simple Model Systems for Examination of Cannabinoid Effects on Genetics, Development and Nervous Systems Using Roundworms (*C. elegans*) and/or Killifish (*Nothobranchius*).

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

Investigate the Effect of THC and Roles of CB2R and Sex on Resistance to a Secondary Systemic *C. albicans* Infection

**Odmara Barreto Chang, MD, PhD | UC San Francisco | San Francisco, CA**

Evaluation of BIS and Levels of Sedation with Common Inhalational Anesthetics in Healthy Volunteers

**Michael DeGregorio, PharmD | Immuno Tess, Inc. | Roseville, CA**

Effects of Cannabinoids on Immune Response in Combination with Immunomodulators: Potential Utility in Cancer Immunotherapy

**MAPS Public Benefit Corporation (MAPS-PBC) | San Jose, CA**

A Phase 1, Open Label, Study of 3,4-Methylenedioxymethamphetamine (MDMA) Tolerability and Pharmacokinetics in Subjects with Moderate Hepatic Impairment Compared to Matched Control Subjects with Normal Hepatic Function (MAPS)

**MAPS Public Benefit Corporation (MAPS-PBC) | San Jose, CA**

A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder of Moderate or Greater Severity (MAPP2)

**Olivier George, PhD | UC San Diego | La Jolla, CA**

Preclinical Testing of CBD for the Treatment of Nicotine Dependence

**Jared Inman, MD | Loma Linda University | Loma Linda, CA**

Quantifying Narcotic Use in Outpatient ENT Procedures

**Walter Kaye, MD | UC San Diego | San Diego, CA**

Evaluation of Psilocybin in Reducing Core Symptoms in Anorexia Nervosa: Safety and Efficacy

**David Kokel, PhD | UC San Francisco | San Francisco, CA**

Assessment of Zebrafish Phenotypic Assays to Model the Toxicology and Behavioral Pharmacology of Synthetic Cannabinoids and Other Psychoactive Compounds

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

Panel Approved Research Project (1)

**Marie Lin, PhD, RPh | Lin-Zhi International, Inc. | Sunnyvale, CA**

Lin-Zhi Immunoassay Development Study

**Thomas Marcotte, PhD | UC San Diego | San Diego, CA**

Effects of Cannabis/Alcohol on Simulated Driving Performance and Field Sobriety Tests

**Fatta Nahab, MD | UC San Diego | La Jolla, CA**

A Double-Blind, Cross-Over, Placebo-Controlled Efficacy and Tolerability Study of Oral Cannabidiol (CBD) and Tetrahydrocannabinol (THC) for Essential Tremor (ET)

**Khanh Nguyen, MD | Loma Linda University Medical Center | Loma Linda, CA**

Assessing Perceived Quality of Care with Differing Pain Management Protocols after Outpatient Otolaryngology Procedures

**Svetlana Nikoulina, PhD | Pharmaron | San Diego, CA**

Determine Exposure of Sponsor's Test Article(s) After Intranasal (IN) and Oral (PO) Administration in Male Beagle Dogs (Crossover)

**Dean Phillips, PhD | Novartis Institute for Functional Genomics | San Diego, CA**

High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays

**Novartis Institute for Functional Genomics | San Diego, CA**

Use of Selected DEA Schedule I Controlled Substances as Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies

**Amir Raz, PhD | Chapman University | Irvine, CA**

Psilocybin Microdosing in Healthy Volunteers: Comparative Effects on Sleep, Brain Activity, Psychosocial, and Cognitive Functioning

**Relmada Therapeutics, Inc. | Coral Gables, FL**

Efficacy and Safety of REL-1017 Monotherapy for Major Depressive Disorder (The RELIANCE-III Study)

**Relmada Therapeutics, Inc. | Coral Gables, FL**

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (The RELIANCE-I Study)

**Pietro Sanna, MD | The Scripps Research Institute | La Jolla, CA**

Neural Substrates of Opiate-HIV Interactions

**Rajkumar Sevak, PhD | UC Los Angeles | Los Angeles, CA**

Human Methamphetamine Self-Administration in a Progressive-Ratio Paradigm

**Ivan Soltesz, PhD | Stanford University | Stanford, CA**

Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy

**Jazz Pharmaceuticals (formerly GW Pharmaceuticals) | Dublin, Ireland**

A Double-blind, Randomized, Placebo-controlled, Parallel-group Trial of the Efficacy and Safety of Nabiximols Oromucosal Spray as Add-on Therapy in Patients with Spasticity Due to Multiple Sclerosis

**Neo Therapeutics | CRO: Premier Research | Covington, LA**

A Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose Study of Adzenys XR-ODT™ in Children Aged 4 to Less Than 6 Years Diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD)

**NIH (National Institutes of Health)/ NIAID | Rockville, MD**

A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate Efficacy, Safety, and Tolerability of JBT-101 in Systemic Lupus Derythematosus

**Waylan Wong, MD | UCI Health (UC Irvine) | Orange, CA**

Outcomes of DSUVIA Administration for Retina Surgery: A Pilot Study

**Jianmin Xu, PhD | Latitude Pharmaceuticals, Inc. | San Diego, CA**

Development of Oral, Injectable and Ophthalmic Formulation Technologies for Cannabidiol (CBD) and Tetrahydrocannabinol (THC)

**Roya Yumul, MD, PhD | Cedars-Sinai Medical Center | Los Angeles, CA**

Intraoperative Ketamine and Methadone for Laminectomy: Effect on Recovery, Postoperative Pain, and Opioid Requirements

## APPENDIX A

### OPEN (through December 31, 2022) 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

**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

**Ziva Cooper, PhD | UC Los Angeles | Los Angeles, CA**

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

**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 Los Angeles | Los Angeles, CA**

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

**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

**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

**Brook Henry, PhD | UC San Diego | San Diego, CA**

Effect of Cannabis Administration and Endocannabinoids on HIV Neuropathic Pain Study - Phase 2

**William Jagust, MD | UC Berkeley | Berkeley, CA**

Dopaminergic Mechanisms Underlying Decision-Making: Academic Human Subjects Research with Schedule II Drug (methylphenidate)

**Sulggi Lee, MD, PhD | UC San Francisco | San Francisco, CA**

Effect of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study

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

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

**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**

Efficacy of Inhaled Cannabis versus Placebo for the Acute Treatment of Migraine: A Randomized, Double-Blind, Placebo-Controlled, Crossover Trial

**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

**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

**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 (PTRD)

**Marc Weintraub, PhD | UC San Diego | 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 | 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

**Joshua Woolley, MD, PhD | UC San Francisco | San Francisco, CA**

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

**Fadel Zeidan, PhD | UC San Diego | La Jolla, CA**

Brain Mechanisms of Cannabis-Based Analgesia

## APPENDIX B

### OPEN (through December 31, 2022) SCHEDULE I AND SCHEDULE II MULTICENTER CLINICAL DRUG TRIAL RESEARCH STUDIES

**Kathleen Angkustsiri, MD | UC Davis Mind Institute | Sacramento, CA**

Evaluating Assessment and Medication Treatment of ADHD in Children with Down Syndrome

**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)

**Compass Pathfinder Limited | CRO: Worldwide Clinical Trials | Cheshire, United Kingdom**

Efficacy and Safety of COMP360 Psilocybin Therapy in Anorexia Nervosa: A Proof-Of-Concept Study

**EmpowerPharm 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

**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)

**MAPS Public Benefit Corporation (MAPS-PBC) | San Jose, CA**

An Intermediate size Multi-Site Expanded Access Program for MDMA-Assisted Psychotherapy for Patients with Treatment-Resistant PTSD (EAMP1)

**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)

**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, Open-Label Study to Assess the Long-Term Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (RELIANCE-OLS)



**Relmada Therapeutics, Inc. | Coral Gables, FL**

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of REL-1017 as Adjunctive Treatment of Major Depressive Disorder (The RELIANCE-II Study)

**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. | CRO: ICON Strategic Solutions | 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

**Vertex Pharmaceuticals, Inc. | CRO: ICON Strategic Solutions | 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

## APPENDIX C

### OPEN (through December 31, 2022) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE USE DISORDER

**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)

**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

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

Emergency Department-Initiated Buprenorphine Validation Trial

**Edythe London, PhD | UC Los Angeles | Los Angeles, CA**  
Cannabidiol as Adjunctive Treatment for Opioid Use Disorder

**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

**Mohammed A. Bari, MD | Cari Health, Inc | San Diego, CA**  
Interstitial Fluid Collection Validation Study

## APPENDIX D

### OPEN (through December 31, 2022) 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**  
MDMA and Memory, Addiction, Social Behavior, Anxiety, and Depression: A Dose-Effect Analysis

**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

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

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

**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)

**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

**Nicholas V. Cozzi, PhD | Alexander Shulgin Research Institute (ASRI) | Berkeley, CA**

Synthesis and Structure-Activity Relationships of Psychoactive Drugs Acting on Biogenic Amine Systems

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

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

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

Effects of LSD on Brain-Wide Neural Activity and Behavior

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

Neural Circuit Dynamics of LSD-Induced Psychosis

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

The Effect of DMT and 5-MeO DMT on Brain-Wide Activity and Behavior

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

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

**Nicholas DiPatrizio, PhD | UC Riverside School of Medicine | 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

**David Paul Dumas, PhD | Amaratek | San Diego, CA**

Low Temperature Plasma Mass Spectroscopy Identification of Aerosols

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

Effects of Psilocybin on Embryonic Development

**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

**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

**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)

**Mazen Kheirbek, PhD | UC San Francisco | San Francisco, CA**

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

**Edward Kisak, PhD | Tioga Research | San Diego, CA**

Research and Early Pharmaceutical Development of a Transdermal Dosage Form of Psilocybin

**Frank Kochinke, PhD | Mycrodose Therapeutics | San Diego, CA**

Sustained Delivery of Psilocybin/Psilocin, LSD, MDMA, and DMT

**Koniku, Inc. | Berkeley, CA**

Development of a Device that Detects Controlled Substances

**Alexander Kuttyrev, 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 (2)

**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

**Pamela A. Maher, PhD | The 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 | Stanford University | Palo Alto, CA**  
The Role of Oxytocin in the Pathogenesis of Autism

**Uri Manor PhD | The Salk Institute | La Jolla, CA**  
Therapeutic Potential and Mechanism of Psychoplastogen Compounds

**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

**Svetlana Nikoulina, PhD | Pharmaron | 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

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

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

**AnaBios Corp | San Diego, CA**  
CardioPRIME®: Adult Human Primary Ventricular Cardiomyocyte Contractility Assay with Ibogaine HCl

**Dilworth (Dula) Parkinson, PhD | Lawrence Berkeley National Laboratory | Emeryville, CA**

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

**Jeanne Paz, PhD | UC San Francisco | San Francisco, CA**

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

**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

**Daniele Piomelli, PhD | UC Irvine | Irvine, CA**

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

**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

**Suzaynn Schick, PhD | UC San Francisco | San Francisco, CA**

Measuring Environmental Tobacco and Cannabis: Pollutants and Exposures

**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

**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

**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

**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

**Deepti Tanjore, PhD | Lawrence Berkeley National Laboratory | Emeryville, CA**

Expression of Phytocannabinoids in Yeast: a High Yield Platform for Low Abundance Natural Products (Phase II)

**Francesca Telese, PhD | UC San Diego | La Jolla, CA**

Epigenetic Regulation of Gene Expression in the Brain

**Kaye Tye, PhD | The 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

**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



**Moonbin Yim, PhD | ARK Diagnostics | Fremont, CA**

Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing

**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 | Malachite Innovations | Rocklin, CA**

Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation

**Yi Zuo, PhD | UC Santa Cruz | Santa Cruz, CA**

Chemical Modulation of Neural Circuits and Plasticity

## APPENDIX E

### STATUTORY AUTHORITY CONCERNING THE RESEARCH ADVISORY PANEL FROM THE CALIFORNIA HEALTH AND SAFETY CODE

**Health and Safety Code section 11213.** Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and Section 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

**Health and Safety Code section 11392.** (Authorized acquisition for use in bona fide research, instruction, or analysis.)

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

**Health and Safety Code section 11480.** (a) The Legislature finds that there is a need to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects.

(b) There is a Research Advisory Panel that consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, the State Public Health Officers, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private 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.

(Section 11480 Cont.)

(c) The Research Advisory Panel shall appoint two special members to the Research Advisory Panel, who shall serve at the pleasure of the Research Advisory Panel only during the period Article 6 (commencing with Section 11260) of Chapter 5 remains effective. The additional members shall be physicians and surgeons, and who are board certified in oncology, ophthalmology, or psychiatry.

(d) The panel shall annually select a chairperson from among its members.

(e) The panel may hold hearings on, and in other ways study, research projects concerning cannabis or hallucinogenic drugs in this state. Members of the panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

(f) The panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of cannabis or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of cannabis pursuant to Section 11478.

(g) The panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of cannabis to the Attorney General.

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

**Health and Safety Code section 11481.** 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.** 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.** 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 various medical conditions who may be suitable participants in research on cannabis.

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

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

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

(Section 11362.9 Cont.)

(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.

(Section 11362.9 Cont.)

(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.

(l)

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

(Section 11362.9 Cont.)

(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.

(Section 11362.9 Cont.)

(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.)

(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.



(Section 11839.3 Cont.)

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

(3) Charge and collect licensure fees. In calculating the licensure fees, the department shall include staff salaries and benefits, related travel costs, and state operational and administrative costs. Fees shall be used to offset licensure and inspection costs, not to exceed actual costs.

(4) Study and evaluate, on an ongoing basis, narcotic treatment programs including, but not limited to, the adherence of the programs, to all applicable laws and regulations and the impact of the programs on the communities in which they are located.

(5) Provide advice, consultation, and technical assistance to narcotic treatment programs to ensure that the programs comply with all applicable laws and regulations and to minimize any negative impact that the programs may have on the communities in which they are located.

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

(7) The director may grant exceptions to the regulations adopted under this chapter if he or she determines that this action would improve treatment services or achieve greater protection to the health and safety of patients, the local community, or the general public. An exception shall not be granted if it is contrary to, or less stringent than, the federal laws and regulations that govern narcotic treatment programs.

(b) It is the intent of the Legislature in enacting this section, in order to protect the general public and local communities, that take-home doses of narcotic replacement therapy medications authorized for use pursuant to Section 11839.2 shall only be provided when the patient is clearly adhering to the requirements of the program, and if daily attendance at a clinic would be incompatible with gainful employment, education, responsible homemaking, retirement or medical disability, or if the program is closed on Sundays or holidays and providing a take-home

(Section 11839.3 Cont.)

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.

(Section 11839.7 Cont.)

(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.

(Section 24172 Cont.)

- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
- (i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

### **Health and Safety Code section 24173. (Informed Consent)**

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

- (a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
- (b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
- (c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:
  - (1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.
  - (2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
  - (3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
  - (4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(Section 24173 Cont.)

- (5) An estimate of the expected recovery time of the subject after 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 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.
  - (11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. 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.

