# FORTY-EIGHTH ANNUAL REPORT

# of the

# RESEARCH ADVISORY PANEL OF CALIFORNIA

# 2018



# PREPARED FOR THE

# LEGISLATURE AND GOVERNOR

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

455 Golden Gate Avenue - Suite 11000 San Francisco, California 94102-7004 https://oag.ca.gov/research

# TABLE OF CONTENTS

Page

LIST OF 2018 PANEL MEMBERS	2
SUMMARY OF 2018 PANEL ACTIVITIES and SELECTED RESEARCH FINDINGS	3
<b>TABLE 1</b> - Research Studies approved in 2018	7
<b>TABLE 2 -</b> Research Studies closed in 2018	15
APPENDICES	•
Appendix A - Currently Open Schedule I and II Non-Human & Academic Human Studies	19
Appendix B - Currently Open Schedule II Clinical Drug Trial Studies	31
Appendix C - Currently Open Research Studies on the Treatment of Controlled Substance Abuse	41
Appendix D - Pertinent Sections - California Health and Safety Code	
<ul> <li>§ 11213 - Persons and researches using controlled substances</li> <li>§ 11480 &amp; 11481 - Research Advisory Panel</li> <li>§ 11603 &amp; 11604 - Attorney General</li> </ul>	43 43 44
§ 24172 - Experimental subject's bill of rights	45
§ 24173 - Informed consent	46

# **2018 PANEL MEMBERS**

# **RESEARCH ADVISORY PANEL OF CALIFORNIA**

The Research Advisory Panel of California (RAPC) consists of the Panel chairman, Executive officer, and the Panel members.

#### Edward P. O'Brien, J.D.

Deputy Attorney General V, State of California AG's Office, San Francisco Panel Chairman, Appointed by the State of California Attorney General

#### Y. Jennifer Ahn, Pharm.D.

Executive Director Appointed by the State of California Attorney General

#### David A. Baron, DO, MSEd

Assistant Dean, USC Keck School of Medicine Appointed by the University of Southern California

#### Chwen-Yuen Angie Chen, MD, FACP

Clinical Assistant Professor, Stanford University School of Medicine Appointed by the California Medical Association (CMA)

#### Patrick R. Finley, Pharm.D.

Professor of Clinical Pharmacy, UCSF School of Pharmacy Appointed by the California State Board of Pharmacy

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

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

#### Laurence R. Upjohn, Pharm.D.

Chief, Science and Education Section, CA Dept of Public Health, Food and Drug Branch Appointed by the State of California Department of Public Health

#### RAPC Website : https://oag.ca.gov/research

#### E-mail contact: jennifer.ahn@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.

#### SUMMARY OF 2018 PANEL ACTIVITIES

During 2018 the Panel reviewed thirty-nine research study submissions. Thirty-five were approved by the Panel. Among the approved studies, twenty-one studies were Academic research studies, fourteen studies were Multi-Center Clinical Drug Trial research studies. No Substance Abuse Treatment research study was approved.

Eleven research studies were completed in 2018, and they were closed on the Panel's records.

At the end of 2018, the Panel was monitoring one hundred and thirty-two research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, significant adverse event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2018 and Table 2 is a list of the studies closed by the Panel in 2018.

#### SELECTED RESEARCH FINDINGS

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

**Dr. D. Andrew Tompkins, MD, MHS** and colleagues at University of California San Francisco, School of Medicine have provided the Panel with the following summary of human research titled "Acute Pain Management in Patients on Opioid Replacement Therapy"

#### A. Specific Aims

The goals of this project are to characterize the analgesic, subjective, and physiologic effects of ketamine combined with hydromorphone in patients on buprenorphine maintenance for opioid use disorder (OUD). There have been no changes to these aims since the original CA RAP approval. We were required to change the format of our CA RAP protocol to meet the UCSF requirements. This also resulted in the identification of an independent medical monitor for the study. Dr. Brad Shapiro. Please see attached current protocol version (1.1).

#### B. Studies and Results

Enrollment and Demographics (Goal 15 Completers):

We received IRB approval for the study from UCSF on 4/12/18 and began recruitment on August 6, 2018. The first in-person screen occurred on October 31, 2018. As of February 28, 2019, four persons have signed consent, one person has qualified for the study, and one person has been randomized. We have no current participants enrolled. We have no study completers. The demographics of those consented are three male and 1 female-to-male transgender; African-American (N=1; 25%), Native American (N=1), Caucasian (N=1), and mixed race (N=1); and mean age of 37.8 +/- 3.8 years (SD). Discharges and Safety Monitoring:

One person has been randomized and received at least one dose of study medications. He was withdrawn after his third study session by the PI due to adverse events from study medication. He developed confusion, nausea, elevated blood pressure, and lightheadedness shortly after receiving his first IM medication dose (ketamine or placebo ketamine). He refused the second IM study medication dose. He was monitored overnight per protocol and the symptoms resolved by the time of discharge the next morning. It was revealed that the participant had a remote history of taking illicit ketamine and having a similar reaction that was not revealed during study screening. After review of the case with Dr. Shapiro, the independent medical monitor, we have decided no changes to the protocol are necessary. We have improved our screening procedures to improve our ability to detect these past negative experiences with ketamine in future study participants. There were no AEs reported by our first participant in sessions 1 or 2.

### Accomplishments

The main accomplishment was starting the study in the past year. We hired an assistant clinical research coordinator, developed all study related policies and procedures, developed and implemented an outreach plan to all known buprenorphine prescribers and clinics in San Francisco, trained all study personnel on the protocol and randomized our first participant.

### C. Plans

The primary plans during Year 2 are to continue enrollment and running study sessions. We then hope to use the results from the first 3 study completers to submit a grant for further funding.

<u>NIH/NIDA</u> has provided the Panel with the following summary of the substance abuse treatment research titled "Phase 2, Multi-Center Trial of Lorcaserin for the Treatment of Cocaine Use Disorder"

The lorcaserin trial is a multi-center, double-blind, placebo-controlled, parallel-group Phase 2 study to evaluate the safety and efficacy of lorcaserin in patients with cocaine use disorder in a 13-week treatment period involving 272 treatment seeking patients. This study was completed on October 12, 2018 with 272 subjects enrolled. There were no findings of safety concerns as reported by the most recent Data Safety Monitoring Board (DSMB) review from December 2018.

The controlled substances inventory log was monitored by a sponsor appointed ICH/GCP trained Clinical Research Associate (CRA) and was maintained at each site and available upon request. There were no substantive changes to this research project to date.

Currently, data cleaning and analysis is ongoing with a final data lock and corresponding final study report pending. Once finalized, the final study report will be distributed accordingly. It is intended that any positive findings from this Phase 2 trial will be confirmed through future definitive Phase 3 trials.

**Dr. Brandon Zipp, Ph.D.** and colleagues at Vitality Biopharma, Inc. has provided the Panel with the following summary of the non-human research titled "Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation"

Vitality Biopharma has had another productive year researching the structures and biosynthesis of cannabinoid glycosides. We have determined the precise molecular structure of VBX-100 and a number of other glycosides of THC, through chemical purification and analysis by 1D and 2D NMR methodologies. This structural information has improved our understanding of the biosynthesis of THC-glycosides by our glucosyltransferase biocatalyst, SrUGT76G1. We have also characterized the molecular structures of a number of cannabidiol glycosides. We are now focused on our lead pharmaceutical candidate, VBX-100, a tri-glycoside of  $\Delta$ 9-tetrahydrocannabinol ( $\Delta$ 9-THC). VBX-100 has demonstrated efficacy in the TNBS-induced ulcerative colitis model in mice, and does not bind to the human cannabinoid receptor 1 (CBR1). This renders VBX-100 inert in the upper gastrointestinal tract, until the sugars can be removed through glucose hydrolase enzyme cleavage in the lumen of the large intestine. We are developing VBX-100 for the treatment of ulcerative colitis, and have carried out a pre-IND meeting with the Food and Drug Administration (FDA) for the development of VBX-100. We anticipate submitting the Investigational New Drug (IND) application in mid 2019, and initiating clinical trials in late 2019.

<u>Corbus Pharmaceuticals</u> has provided the Panel with the following Annual Progress Report of multicenter clinical drug trial research titled "A Phase 2, Double-blind, Randomized, Placebo-controlled Multicenter Study to Evaluate Safety, Tolerability, Efficacy, and Pharmacokinetics of JBT-101 in Diffuse Cutaneous Systemic Sclerosis Study JBTIOI-SSc-001 completed Part A Blinded enrollment with last subject last visit taking place on 10-0ctober-2016. Study-wide, forty-three subjects were enrolled and thirty-eight completed. Site 1007, Stanford University, enrolled a total seven subjects,

5

five subjects completed the study. Site 1003, Arthritis Association of Southern California, enrolled a total of three subjects, all three completed the study. Subjects who have completed Part A of the JBTIOI-SSc-001 study had the option to enroll into the Part B Open Label Extension (OLE) that is currently ongoing under Protocol JBTIOI-SSc-001 Version 3 dated 13-June-2017. Nationally, there were 36 subjects enrolled with a current total of 30 subjects ongoing. There are 3 subjects currently enrolled in the Part BOLE at site 1003 and 3 subjects currently enrolled at site 1007 for a total of six subjects at California sites.

There have been no new significant safety findings during this reporting period. No study drug related serious adverse events have been reported.

#### TABLE 1

### RESEARCH STUDIES APPROVED IN 2018

<u>PI/Sponsor</u>

Marc Azar, Ph.D. Behavioral Pharma, Inc. La Jolla, CA

Marc Azar, Ph.D. Behavioral Pharma, Inc. La Jolla, CA

Asser Bassyouni, M.S. Pfizer, Inc. San Diego, CA

Michael DeGregorio, Pharm.D. Immuno Tess, Inc. Roseville, CA

Sirine C. Fakra, Ph.D. Lawrence Berkeley National Laboratory Emeryville, CA

Neil K. Garg, Ph.D. UCLA Los Angeles, CA

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

Effects of Client's Test Compound on Cue-Induced Reinstatement of Heroin-Seeking Behavior

Effects of Test Compound on Rats Trained to Intravenously Self-Administer Heroin

Understanding the Translation of the Response of the CB1 Agonist

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

Evaluation of Industrial Hemp for Phytoremediation and Se Biofortification Applications

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

7

#### <u>PI/Sponsor</u>

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA Preclinical Testing of CBD for the Treatment of Nicotine Dependence

A. Goonawardena, Ph.D. SRI International Menlo Park, CA Cannabinoid Regulation on Resting State Quantitative EEG, Sleep and Cognition

Judith Hellman, M.D. UCSF Dept of Anesthesia & Perioperative Care San Francisco, CA

Sulggi A. Lee, MD, PhD UCSF San Francisco, CA

Mallory Loflin, Ph.D. San Diego Veterans Affairs Medical Center San Diego, CA Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury

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

Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

8

### PI / Sponsor

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

Faith Kennedy McDaniel, Ph.D. Koniku Inc. Berkeley, CA

Rachel Eshima McKay, M.D. UCSF San Francisco, CA

Lupe Mejorado, Ph.D. Alere San Diego, Inc. San Diego, CA

Fatta B. Nahab, M.D. UC San Diego La Jolla, CA Development of a Device that Detects Controlled Substances

Evaluation of Pupillary Unrest in Prediction of Opioid Induced Respiratory Depression

In Vitro Assay for the Synthetic Cannabinoids Belonging to JWH and Pinaca Family

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

Joy Phillips, Ph.D. San Diego State University San Diego, CA

Daniele Piomelli, Ph.D. UC Irvine Irvine, CA Effect of Cannabis Inhalation on Respiratory Inflammation and Immune Function

 Effect of Adolescent Cannabis Exposure in Adults Mice and Rats
 In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

PI / Sponsor

Birgit Puschner, DVM, PhD UC Davis School of Veterinary Medicine Davis, CA

Pietro Paolo Sanna, M.D. The Scripps Research Institute La Jolla, CA

Mehrdad Shamloo, Ph.D. Stanford University Palo Alto, CA

Rama Voladri, Ph.D. Codexis, Inc. Redwood City, CA

Alkermes Waltham, MA

Arbor Pharmaceuticals CRO: Rho Inc. Chapel Hill, NC

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

Analysis of Cannabinoids in Help Oil Veterinary Treats/Supplements

Neural Substrates of Opiate-HIV Interactions

Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases

Transaminase Evolution Proposal for Genentech. Engineering ATA-P2-A07 for a synthesis of G03044577

A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder (ALK5461-218)

A Multicenter, Fixed-Dose, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of AR19 (Amphetamine Sulfate) in Adult Subjects (Ages 18-55) with Attention Deficit Hyperactivity Disorder (ADHD (AR19.004)

### PI / Sponsor

Avenue Therapeutics, Inc. New York, NY

A Phase 3, Multicenter, Randomized, Double-Blind, Three-Arm Study to Evaluate the Efficacy and Safety of Tramadol Infusion (AVE-901) Versus Placebo and Morphine in the Management of Postoperative Pain Following Abdominoplasty (AVE-901-103)

Title of Study / Clinical Drug

Trial Protocol

A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of BTX 1503 in Patients with Moderate to Severe Acne Vulgaris (BTX.2018.001)

A Multicenter, Randomized, Double-Bind, Placebo-Controlled Phase 3 Trial of Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis (JBT101-DM-002)

A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution as Adjunctive Therapy with Vigabatrin as Initial Therapy in Patients with Infantile Spasms (INS011-16-082)

#### Botanix

CRO: Premier Research Research Triangle Park, NC

Corbus Norwood, MA

INSYS Chandler, AZ

PI / Sponsor

INSYS Therapeutics Chandler, AZ

INSYS Therapeutics Chandler, AZ

MAPS Santa Cruz, CA

Noven Pharmaceuticals New York, NY

Receptor Life Sciences CRO: WCCT Global Cypress, CA

# Title of Study / Clinical Drug Trial Protocol

A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution for the Treatment of Patients with Prader-Willi Syndrome (INS011-16-085)

A Multicenter, Open-Label Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Patients with Prader-Willi Syndrome (INS011-17-115)

Panel Approved Research Study

A Randomized, Multiple-Dose, Open-Label, 4-Week Study to Characterize the Pharmacokinetics, Cumulative Irritation, Safety, and Tolerability of d-Amphetamine Transdermal System (d-ATS) in Adults Diagnosed with ADHD (N25-015)

A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Health Adult Participants (RC-2018/01)

#### <u>PI / Sponsor</u>

Relmada Therapeutics, Inc. CRO: Syneos Health Cary, NC

West-Ward Pharmaceuticals Columbus, OH <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

A Phase 2a, Multicenter, Randomized, Double-Blind, Placebo Controlled, 3 Arm Study to Assess the Safety, Tolerability, PK Profile, and Symptom Response of a 7-Day Dosing with REL 1017 25 mg QD and 50 mg QD as Adjunctive Therapy in the Treatment of Patients Diagnosed with Major Depressive Disorder

(REL-1017-202)

A Multicenter, Open-Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 Years Old Through 17 Years Old with Postoperative Pain (MORP-OS+T-(2-17)-SPK-2)

Zynerba Pharmaceuticals, Pty. Ltd. Southbank, VIC Australia

A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome (ZYN2-CL-016)

13

### TABLE 2

### **RESEARCH STUDIES CLOSED IN 2018**

#### <u>Sponsor / PI</u>

Judith Hellman, M.D. UCSF San Francisco, CA

Gunjan Junnarkar, Ph.D. Jazz Pharmaceuticals Menlo Park, CA

Lori Olson, M.S. SRI International Menlo Park, CA

Alkermes Waltham, MA

Alkermes Waltham, MA

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

Cannabinoid-Dependent Modulation of the Innate Immune Response to Infection and Injury

Oxybate Research

Identification and isolation of specific pesticides from cannabinoid oils

A Phase 2, Randomized, Double-Blind Study to Evaluate Efficacy, Safety, and Tolerability of ALKS3831 in Subjects with Schizophrenia with Alcohol Use Disorder (ALKS3831-401)

A Phase 3 Efficacy and Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALK5461-207)

Sponsor / PI

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

Alkermes Waltham, MA

INSYS Therapeutics Chandler, AZ

Maps Santa Cruz, CA

Shire CRO: PPD Morrisville, NC A Phase 3 Study to Determine the Antipsychotic Efficacy and Safety of ALKS 3831 in Adult Subjects with Acute Exacerbation of Schizophrenia (ALK3831-A305)

A Phase 2, Randomized, Open Label, Multiple-Dose, Comparator, Parallel-Group, Safety and Tolerance Study of Buprenorphine Sublingual Spray (0.5mg TID) versus Standard of Care Post-Operative Narcotic Therapy for the Treatment of Post-Operative Pain (INS005-17-111)

Panel Approved Research Study

A Phase 3, Open-label, Multicenter, 12-Month Safety and Tolerability Study of SHP465 in Children Aged 4 to 12 Years Diagnosed with Attention-Deficit/ Hyperactivity Disorder (ADHD) (SHP465-308)

# Sponsor / PI

## Shire CRO: PPD Morrisville, NC

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

A Phase 3, Randomized, Double-blind, Multicenter, Placebo-controlled, Fixed-Dose, Safety, and Efficacy Study of SHP465 in Children Aged 6-12 Years with Attention-Deficit/Hyperactivity Disorder (ADHD) (SHP465-309)

Vertex Pharmaceuticals Boston, MA A Phase 2 randomized, Double-Bind, Placebo-Controlled, 3-Arm, Parallel-Design Study of the Efficacy and Safety of VX-150 for Acute Pain Following Bunionectomy (VX16-150-103)

# Sponsor / PI

# <u>Title of Study / Clinical Drug</u> <u>Trial Protocol</u>

#### <u>APPENDIX A</u>

## CURRENTLY OPEN (through December 31, 2018) SCHEDULE I AND SCHEDULE II NON-HUMAN AND ACADEMIC HUMAN RESEARCH STUDIES

## **Principal Investigator**

## Title of Study

Marc Azar, Ph.D. Behavioral Pharma, Inc. La Jolla, CA Effects of Client's Test Compound on Cue-Induced Reinstatement of Heroin-Seeking Behavior

Marc Azar, Ph.D. Behavioral Pharma, Inc. La Jolla, CA

Richard Baldwin, Ph.D. nanoComposix San Diego, CA Effects of Test Compound on Rats Trained to Intravenously Self-Administer Heroin

Biosensor for the Detection of Synthetic Cannabinoids

Nelson Barton, Ph.D. Genomatica, Inc. San Diego, CA

Asser Bassyouni, M.S. Pfizer, Inc. San Diego, CA Microbial Processes for the Manufacture of Specialty Chemicals

Understanding the Translation of the Response of the CB1 Agonist

19

# Principal Investigator

Neal L. Benowitz, M.D. UCSF San Francisco, CA

Nancy E. Buckley, Ph.D. CA State Polytech University Pomona, CA

Nicholas Butowski, M.D. UCSF Neurological Surgery San Francisco, CA

Jeremy Caldwell, Ph.D. Genomics Institute Novartis Foundation San Diego, CA

John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA

Kent Chu YJ Bio-Products Cordova, CA

# Title of Study

Intake and Pharmacokinetics of THC Vaped from Electronic Cigarettes

Investigating the effect of THC on the susceptibility to systemic C. Albicans infection in mice treated with an anti-cancer drug

CBD Developmental Research Project

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

Molecular Evolution of Human Cocaine Catalysis

Immunochromatographic Test Device for THC and LSD

### Principal Investigator

Title of Study

Laura Colin Biostride, Inc. Redwood City, CA

Nissar A. Darmani, Ph.D. College of Osteo Medicine Western University of health Sciences Pomona, CA

Michael DeGregorio, Pharm.D. Immuno Tess, Inc. Roseville, CA

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

Davide Dulcis, Ph.D. UCSD La Jolla, CA

Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA Panel Approved Research Study

Project 1: Mechanisms of vomiting induced by chemotherapeutics, related emetics, & GI disorders. Project 2: Development changes in monoamine function following prenatal & early postnatal exposure to serotonergic altering drugs in mice.

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

Neural Circuit Dynamics of LSD-Induced Psychosis

Effects of Neonatal Nicotine Exposure on Dopamine Neurons Affecting Consumption of Substances of Abuse in the Adult

Dopamine involvement in Opiate and Stimulant Reinforcement

#### Principal Investigator

Sirine C. Fakra, Ph.D. Lawrence Berkeley National Laboratory Emeryville, CA

Christie Fowler, Ph.D. UC Irvine Irvine, CA

Neil K. Garg, Ph.D. UCLA Los Angeles, CA

Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA

Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA

Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA

Mark A. Geyer, Ph.D. Dept of Psychiatry, UCSD La Jolla, CA

Alidad Ghiassi, M.D. Keck School of Medicine USC

# Title of Study

Evaluation of Industrial Hemp for Phytoremediation and Se Biofortification Applications

Mechanisms of Drug Reinforcement

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

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

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

Preclinical Testing of CBD for the Treatment of Nicotine Dependence

Effects of Cannabidiol on Mania-relevant Locomotor and Investigatory Behavior

A Randomized Trial Comparing Ibuprofen Plus Acetaminophen Versus Oxycodone After Outpatient Soft Tissue Hand Surgery

### Principal Investigator

## Title of Study

A. Goonawardena, Ph.D. SRI International Menlo Park, CA

Judith Hellman, M.D. UCSF Dept of Anesthesia & Perioperative Care San Francisco, CA

Brook Henry, Ph.D. UC San Diego San Diego, CA

Kanthi Hettiarachchi, Ph.D. SRI International Menlo Park, CA Cannabinoid Regulation on Resting State Quantitative EEG, Sleep and Cognition

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

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

Analysis of Controlled Substances

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

Kim D. Janda, Ph.D. The Scripps Research Institute San Diego, CA

Jay Keasling, Ph.D. Joint Bioenergy Institute Emeryville, CA Vaccines for the Treatment of Opiate Addiction

Immunopharmaco Therapy for Methamphetamine Addiction

Engineering the Industrial Microbe Sacccharomyces Cerevisiae for Biosyntheris of Cannabinoids

# Principal Investigator

### Sulggi A. Lee, MD, PhD UCSF San Francisco, CA

Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA

Marie Lin, Ph.D. Lin-Zhi International Sunnyvale, CA

Mallory Loflin, Ph.D. San Diego Veterans Affairs Medical Center San Diego, CA

# <u>Title of Study</u>

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

Panel Approved Research Study

### Panel Approved Research Study

Panel Approved Research Study

Panel Approved Research Study

Lin-Zhi Immunoassay Development Study

Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

### Principal Investigator

<u>Title of Study</u>

Stephen Mahler, Ph.D. UC Irvine Irvine, CA

Robert Malenka, M.D. School of Medicine Stanford University Palo Alto, CA Neural Circuits Underlying Motivation and Addiction

The Role of Oxytocin in the Pathogenesis of Avtism

Thomas Marcotte, Ph.D. UCSD Health Care System San Diego, CA A Randomized, Controlled Trial of Cannabis in Healthy Volunteers Evaluating Simulated Driving, Field Performance Tests and Cannabinoid Levels

Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA

Faith Kennedy McDaniel, Ph.D. Koniku Inc. Berkeley, CA

Sara Mednick, Ph.D. UC Riverside Riverside, CA

Lupe Mejorado, Ph.D. Alere San Diego, Inc. San Diego, CA Development of a Device that Detects Controlled Substances

Panel Approved Research Study

The Effects of Zolpidem and Dextroamphetamine on Cognitive Performance

In Vitro Assay for the Synthetic Cannabinoids Belonging to JWH and Pinaca Family

Principal Investigator

Byung-Sook Moon ARK Freemont, CA

Stephen Morairty, Ph.D. SRI International Menlo Park, CA

Heinz Moser, Ph.D. Novartis Institute Emeryville, CA

Alysson Muotri, Ph.D. UC San Diego La Jolla, CA

Fatta B. Nahab, M.D. UC San Diego La Jolla, CA

David E. Olson, Ph.D. UC Davis Davis, CA

Lori Olson, M.S. SRI International Menlo Park, CA

# Title of Study

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

Panel Approved Research Study

Synthesis and Optimization of Novel Therapeutics

The Impact of CBD/THC on Human Neurodevelopment

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

Chemical Modulation of Neural Plasticity, Learning and Memory

Identification and isolation of specific pesticides from cannabinoid oils

# Principal Investigator

Title of Study

Jeanne Paz, Ph.D. The J. David Gladstone Institutes San Francisco, CA

Mark Peterman, Ph.D. OndaVia Hayward, CA

Joy Phillips, Ph.D. San Diego State University San Diego, CA

Daniele Piomelli, Ph.D. UC Irvine Irvine, CA

Birgit Puschner, DVM, PhD UC Davis School of Veterinary Medicine Davis, CA

Richard Reznichek, M.D. Harbor-UCLA Los Angeles, CA The Effects of Developmental Cannabis Exposure on Brain and Behavioral Development in Rats

Development of a Rapid and Field-Ready Heroin analysis Tool

Effect of Cannabis Inhalation on Respiratory Inflammation and Immune Function

1. Effect of Adolescent Cannabis Exposure in Adults Mice and Rats

2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

Analysis of Cannabinoids in Help Oil Veterinary Treats/Supplements Panel Approved Research Study

Panel Approved Research Study

Principal Investigator

# Title of Study

Pietro Paolo Sanna, M.D. The Scripps Research Institute La Jolla, CA

David Schubert, Ph.D. Salk Institute La Jolla, CA

Philip Schwartz, Ph.D. Children's Hospital of Orange County Orange, CA

Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA

Mehrdad Shamloo, Ph.D. Stanford University Palo Alto, CA

Ivan Soltesz, Ph.D. Stanford University Stanford, CA Neural Substrates of Opiate-HIV Interactions

The Identification of Neuroprotective Compounds in Cannabis

## Effect of Receptor Activation on Human Neuron Stem Cell Function

Safety and Initial Efficacy of Lisdexamfetamine for Modifying the Behavioral Effects of Intravenous Methamphetamine in Humans

Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases

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

### Principal Investigator

<u>Title of Study</u>

Matthew L. Springer, Ph.D. UCSF San Francisco, CA

Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA

Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA

Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA

Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA

Francesca Telese, Ph.D. UCSD La Jolla, CA Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers

Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol

Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs

Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs

Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol

Epigenetic Regulation of Gene Expression in the Brain

Panel Approved Research Study

Jeff Ubersax Demetrix, Inc. Emeryville, CA

Rama Voladri, Ph.D. Codexis, Inc. Redwood City, CA Transaminase Evolution Proposal for Genentech. Engineering ATA-P2-A07 for a synthesis of G03044577

Principal Investigator

Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA

Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA

Joshua Woolley, MD, PhD UCSF VA Medical Ct. San Francisco, CA

Matthew Worley, Ph.D. UCSD La Jolla, CA

Roya Yumul Cedars-Sinai Medical Ct. Los Angeles, CA

Brandon Zipp, Ph.D. Vitality Biopharma, Inc. Los Angeles, CA

### <u>Title of Study</u>

Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol

Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol

Psilocybin-Assisted Group Therapy for Demoralization in Long-Term Aids Survivors

Behavioral Economic Mechanisms of ' Prescription Opioid Addiction in Chronic Pain

Intra-operative ketamine and methadone for laminectomy: effect on recovery, postoperative pain, and opioid requirements

Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation

#### APPENDIX B

### CURRENTLY OPEN (through December 31, 2018) SCHEDULE II CLINICAL DRUG TRIAL STUDIES

# <u>Sponsor</u>

Alkermes, Inc.

Waltham, MA

# Description or Title of Clinical Drug Trial Protocol

A Study to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform or Bipolar I Disorder Who are Early in Their Illness (ALK3831-A307)

Alkermes, Inc. Waltham, MA

Alkermes, Inc.

Waltham, MA

A Phase 3 Study to Assess the Long Term Safety, Tolerability, and Durability of Treatment Effect of ALKS 3831 in Subjects with Schizophrenia, Schizophreniform Disorder, or Bipolar I Disorder (ALK3831-A308)

A Phase 3b Efficacy and Safety Study of Adjunctive ALKS5461 in Treatment Refractory Major Depressive Disorder (ALK5461-217)

Alkermes, Inc. Waltham, MA A Phase 3 E & S Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-208)

#### **Sponsor**

Alkermes, Inc. Waltham, MA

Alkermes, Inc. Waltham, MA

Alkermes, Inc. Waltham, MA

Alkermes, Inc.

Waltham, MA

Description or Title of Clinical Drug Trial Protocol

A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder (ALK5461-218)

A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia (ALK3831-A303)

A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A306)

A Phase 1 Study to Evaluate the Effect of Multiple Doses of ALKS 3831 on QTc interval in Subjects with Schizophrenia (ALK3831-A109)

### <u>Sponsor</u>

Alkermes, Inc. Waltham, MA

Alkermes, Inc. Waltham, MA

Arbor Pharmaceuticals CRO: Rho Inc. Chapel Hill, NC

Avenue Therapeutics, Inc. New York, NY

# Description or Title of Clinical Drug Trial Protocol

A Randomized, Double-Blind, Parallel-Group Study in Healthy Subjects to Characterize Insulin Sensitivity and Lipid Metabolism in Response to Treatment with ALKS 3831 and Olanzapine (ALK3831-A108)

A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A304)

A Multicenter, Fixed-Dose, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of AR19 (Amphetamine Sulfate) in Adult Subjects (Ages 18-55) with Attention Deficit Hyperactivity Disorder (ADHD (AR19.004)

A Phase 3, Multicenter, Randomized, Double-Blind, Three-Arm Study to Evaluate the Efficacy and Safety of Tramadol Infusion (AVE-901) Versus Placebo and Morphine in the Management of Postoperative Pain Following Abdominoplasty (AVE-901-103)

<u>Sponsor</u>

Botanix CRO: Premier Research Research Triangle Park, NC

# Description or Title of Clinical Drug Trial Protocol

A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of BTX 1503 in Patients with Moderate to Severe Acne Vulgaris (BTX.2018.001)

CNS Therapeutics CRO: Social & Scientific Systems

Panel Approved Research Study

CNS Therapeutics CRO: Social & Scientific Systems

Corbus Pharmaceuticals Norwood, MA

Corbus Pharmaceuticals Norwood, MA Panel Approved Research Study

A Multicenter, Randomized, Double-Bind, Placebo-Controlled Phase 3 Trial of Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis (JBT101-DM-002)

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate Efficacy and Safety of Lenabasum in Diffuse Cutaneous Systemic Sclerosis (JBT101-SSc-002)

## **Sponsor**

Flamel Ireland CRO: INC Research Austin, TX

## <u>Description or Title</u> of Clinical Drug Trial Protocol

A Double-Blind, Randomized, Placebo-Controlled, Two Arm Multi-Center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy

(CLFT218-1501)

Panel Approved Research Study

Grunenthal/Janssen CRO: inVentiv Cary, NC

GW Cambridge, UK

Panel Approved Research Study

GW Cambridge, UK

### GW

Cambridge, UK

INSYS Therapeutics Chandler, AZ Panel Approved Research Study

Panel Approved Research Study

A Phase 2, Open-Label, Dose-Finding Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Pediatric Patients with Treatment-Resistant Childhood Absence Seizures (INS011-17-103)
<u>Sponsor</u>

INSYS Therapeutics Chandler, AZ

INSYS Therapeutics Chandler, AZ

INSYS Therapeutics Chandler, AZ

INSYS Therapeutics Chandler, AZ

# Description or Title of Clinical Drug Trial Protocol

A Multicenter, Open-Label, Flexible Dose Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution as in Pediatric Patients with Treatment-Resistant Childhood Absence Seizures (INS011-17-113)

A Multicenter, Open-Label Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Patients with Prader-Willi Syndrome (INS011-17-115)

A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution for the Treatment of Patients with Prader-Willi Syndrome (INS011-16-085)

A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution as Adjunctive Therapy with Vigabatrin as Initial Therapy in Patients with Infantile Spasms (INS011-16-082)

<u>Sponsor</u>

INSYS Therapeutics Chandler, AZ

## Description or Title of Clinical Drug Trial Protocol

A multicenter, open-label, flexible dose study to assess the long-term safety of pharmaceutical Cannabidiol Oral Solution as an adjunctive treatment for pediatric and adult subjects with a treatment-resistant seizure disorder who complete INS011-14-024, INS011-14-025, or INS011-14-029 (INS011-14-030)

Jazz Pharmaceuticals CRO: Quintiles Overland Parks, KS A Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of JZP-258 in Subjects with Narcolepsy with Cataplexy (15-006)

MAPS Santa Cruz, CA Panel Approved Research Study

MAPS Santa Cruz, CA

NIH/NIAID Rockville, MD Panel Approved Research Study

A Phase 2, Double-blind, Randomized, Placebo-controlled Multicenter Study to Evaluate Efficacy, Safety, and Tolerability of JBT-101 in Systemic Lupus Erythematosus (ALE09)

<u>Sponsor</u>

Noven New York City, NY

Pfizer CRO: ICON New York, NY

Pfizer CRO: ICON New York, NY

Purdue CRO: PRA Raleigh, NC

Receptor Life Sciences CRO: WCCT Global Cypress, CA

# Description or Title of Clinical Drug Trial Protocol

A Randomized, Multiple-Dose, Open-Label, 4-Week Study to Characterize the Pharmacokinetics, Cumulative Irritation, Safety, and Tolerability of d-Amphetamine Transdermal System (d-ATS) in Adults Diagnosed with ADHD (N25-015)

### Panel Approved Research Study

Panel Approved Research Study

A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel Group, Laboratory Classroom Study to Evaluate the Safety and Efficacy of PRC-063 Compared to Placebo in Children (6-12 years of age) with ADHD (063-015)

A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Health Adult Participants (RC-2018/01)

Sponsor

Recro Pharma Malvern, PA

Relmada Therapeutics, Inc. CRO: Syneos Health Cary, NC

## Description or Title of Clinical Drug Trial Protocol

A Phase 2, Randomized, Double-Blind, Placebo- and Active-Controlled, Evaluation of the Efficacy and Safety of DEX-IN Following Painful Outpatient Procedures (REC-17-023)

Phase 2a, Multicenter, Randomized, Double-Blind, Placebo Controlled, 3 Arm Study to Assess the Safety, Tolerability, PK Profile, and Symptom Response of a 7-Day Dosing with REL 1017 25 mg QD and 50 mg QD as Adjunctive Therapy in the Treatment of Patients Diagnosed with Major Depressive Disorder (REL-1017-202)

Shire CRO: PPD

San Diego, CA

Panel Approved Research Study

Shire CRO: PPD San Diego, CA

Panel Approved Research Study

### **Sponsor**

West-Ward Pharmaceuticals CRO: Premier Research Columbus, OH

# Description or Title of Clinical Drug Trial Protocol

A Multicenter, Open-Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 Years Old Through 17 Years Old with Postoperative Pain (MORP-OS+T-(2-17)-SPK-2)

Zynerba Pharmaceuticals, Pty. Ltd. Southbank, VIC Australia

A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome (ZYN2-CL-016)

#### APPENDIX C

### CURRENTLY OPEN *(December 31, 2018)* RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

### Investigator or Sponsor

# Description or Title of Research Study

Keith Heinzerling, M.D. UCLA Los Angeles, CA

Keith Heinzerling, M.D. UC Los Angeles Los Angeles, CA

Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA

Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA

NIDA/NSC/NIH Bethesda, MD Randomized Trial of Ibudilast for Methamphetamine Dependence

Phase 1 Safety-Interaction Study of Pomaglumetad Methionil for Methamphetamine Use Disorder

Varenicline for Methamphetamine Dependence

Phase I Safety Interaction Trial of Ibudilast with Methamphetamine

Phase 2, Multi-Center Trial of Lorcaserin for the Treatment of Cocaine Use Disorder (NIDA/VA CS #1033)

### Investigator or Sponsor

NIDA/NSC/NIH Bethesda, MD

# Description or Title of Research Project

Comparing Treatments for HIV-Infected Opioid Users in an Integrated Care Effectiveness Study (CHOICES) Scale-Up (NIDA CTN 0067)

NIDA The EMMES Corp. Rockville, MD

NIDA/CTN Rockville, MD Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT) (0051)

Accelerated Development of Additive Pharmacotherapy Treatment (ADAPT-2) for Methamphetamine Use Disorder (NIDA CTN 0068)

#### APPENDIX D

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

**§ 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 § 11480 and § 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 § 11480 or § 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

**§ 11480.** The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, 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 § 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.

The Panel shall annually select a chairman from among its members.

#### § 11480. Cont.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana 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.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to § 11478.

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 marijuana to the Attorney General.

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.

**§ 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.

**§ 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 proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

**§ 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.

§ 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 § 24175, this list shall include, but not be limited to the subject's right to:

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

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

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

#### § 24172. Cont.

(i) Be given a copy of the signed and dated written consent form as provided for by  $\S 24173$  or  $\S 24178$ .

(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.

§ 24173. Informed consent

As used in this chapter, "informed consent" means the authorization given pursuant to § 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 § 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 § 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 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 § 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in § 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 § 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.

#### § 24173. Cont.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(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.

#### § 24173. Cont.

(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 § 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 § 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.