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
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https://oag.ca.gov/research

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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.
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Appointed by the State of California Attorney General

David A. Baron, DO, MSEd
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Appointed by the University of Southern California

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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

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

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.

NIH/NIDA 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 Δ9-tetrahydrocannabinol (Δ9-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.

Corbus Pharmaceuticals 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 JBTlOl-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,

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 JBTlOl-SSc-001 study had the option to enroll into the Part B Open Label Extension (OLE) that is currently ongoing under Protocol JBTlOl-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

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
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	Effects of Test Compound on Rats Trained to Intravenously Self-Administer Heroin
Asser Bassyouni, M.S. Pfizer, Inc. San Diego, CA	Understanding the Translation of the Response of the CB1 Agonist
Michael DeGregorio, Pharm.D. Immuno Tess, Inc. Roseville, CA	Effects of Cannabinoids on Immune Response in Combination with Immunomodulators: Potential Utility in Cancer Immunotherapy
Sirine C. Fakra, Ph.D. Lawrence Berkeley National Laboratory Emeryville, CA	Evaluation of Industrial Hemp for Phytoremediation and Se Biofortification Applications
Neil K. Garg, Ph.D. UCLA Los Angeles, CA	Optical and Electrochemical Detection of Tetrahydrocannabinol (THC) Towards a Functional Quantitative Breathalyzer

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
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	Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury
Sulggi A. Lee, MD, PhD UCSF San Francisco, CA	Effect of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study
Mallory Loflin, Ph.D. San Diego Veterans Affairs Medical Center San Diego, CA	Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Faith Kennedy McDaniel, Ph.D. Koniku Inc. Berkeley, CA	Development of a Device that Detects Controlled Substances
Rachel Eshima McKay, M.D. UCSF San Francisco, CA	Evaluation of Pupillary Unrest in Prediction of Opioid Induced Respiratory Depression
Lupe Mejorado, Ph.D. Alere San Diego, Inc. San Diego, CA	In Vitro Assay for the Synthetic Cannabinoids Belonging to JWH and Pinaca Family
Fatta B. Nahab, M.D. 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)
Joy Phillips, Ph.D. San Diego State University San Diego, CA	Effect of Cannabis Inhalation on Respiratory Inflammation and Immune Function
Daniele Piomelli, Ph.D. UC Irvine Irvine, CA	1. Effect of Adolescent Cannabis Exposure in Adults Mice and Rats 2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Birgit Puschner, DVM, PhD UC Davis School of Veterinary Medicine Davis, CA	Analysis of Cannabinoids in Help Oil Veterinary Treats/Supplements
Pietro Paolo Sanna, M.D. The Scripps Research Institute La Jolla, CA	Neural Substrates of Opiate-HIV Interactions
Mehrdad Shamloo, Ph.D. Stanford University Palo Alto, CA	Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases
Rama Voladri, Ph.D. Codexis, Inc. Redwood City, CA	Transaminase Evolution Proposal for Genentech. Engineering ATA-P2-A07 for a synthesis of G03044577
Alkermes Waltham, MA	A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder (ALK5461-218)
Arbor Pharmaceuticals CRO: Rho Inc. Chapel Hill, NC	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)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
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)
Botanix CRO: Premier Research Research Triangle Park, NC	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)
Corbus Norwood, MA	A Multicenter, Randomized, Double-Bind, Placebo-Controlled Phase 3 Trial of Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis (JBT101-DM-002)
INSYS Chandler, AZ	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)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
INSYS Therapeutics Chandler, AZ	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)
INSYS Therapeutics Chandler, AZ	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)
MAPS Santa Cruz, CA	Panel Approved Research Study
Noven Pharmaceuticals New York, NY	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)
Receptor Life Sciences CRO: WCCT Global Cypress, CA	A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Health Adult Participants (RC-2018/01)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Relmada Therapeutics, Inc. CRO: Syneos Health Cary, NC	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)
West-Ward Pharmaceuticals Columbus, OH	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)

Table 1 Cont.

TABLE 2

RESEARCH STUDIES CLOSED IN 2018

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Judith Hellman, M.D. UCSF San Francisco, CA	Cannabinoid-Dependent Modulation of the Innate Immune Response to Infection and Injury
Gunjan Junnarkar, Ph.D. Jazz Pharmaceuticals Menlo Park, CA	Oxybate Research
Lori Olson, M.S. SRI International Menlo Park, CA	Identification and isolation of specific pesticides from cannabinoid oils
Alkermes Waltham, MA	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)
Alkermes Waltham, MA	A Phase 3 Efficacy and Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALK5461-207)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Alkermes Waltham, MA	A Phase 3 Study to Determine the Antipsychotic Efficacy and Safety of ALKS 3831 in Adult Subjects with Acute Exacerbation of Schizophrenia (ALK3831-A305)
INSYS Therapeutics Chandler, AZ	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)
Maps Santa Cruz, CA	Panel Approved Research Study
Shire CRO: PPD Morrisville, NC	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)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Shire CRO: PPD Morrisville, NC	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)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol

APPENDIX A

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	Effects of Test Compound on Rats Trained to Intravenously Self-Administer Heroin
Richard Baldwin, Ph.D. nanoComposix San Diego, CA	Biosensor for the Detection of Synthetic Cannabinoids
Nelson Barton, Ph.D. Genomatica, Inc. San Diego, CA	Microbial Processes for the Manufacture of Specialty Chemicals
Asser Bassyouni, M.S. Pfizer, Inc. San Diego, CA	Understanding the Translation of the Response of the CB1 Agonist

Appendix A Cont.

Principal Investigator	Title of Study
Neal L. Benowitz, M.D. UCSF San Francisco, CA	Intake and Pharmacokinetics of THC Vaped from Electronic Cigarettes
Nancy E. Buckley, Ph.D. CA State Polytech University Pomona, CA	Investigating the effect of THC on the susceptibility to systemic C. Albicans infection in mice treated with an anti-cancer drug
Nicholas Butowski, M.D. UCSF Neurological Surgery San Francisco, CA	CBD Developmental Research Project
Jeremy Caldwell, Ph.D. Genomics Institute Novartis Foundation San Diego, CA	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays
John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA	Molecular Evolution of Human Cocaine Catalysis
Kent Chu YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD

Principal Investigator	Title of Study
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research Study
Nissar A. Darmani, Ph.D. College of Osteo Medicine Western University of health Sciences Pomona, CA	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.
Michael DeGregorio, Pharm.D. Immuno Tess, Inc. Roseville, CA	Effects of Cannabinoids on Immune Response in Combination with Immunomodulators: Potential Utility in Cancer Immunotherapy
Karl Deisseroth, MD, PhD Stanford University Palo Alto, CA	Neural Circuit Dynamics of LSD-Induced Psychosis
Davide Dulcis, Ph.D. UCSD La Jolla, CA	Effects of Neonatal Nicotine Exposure on Dopamine Neurons Affecting Consumption of Substances of Abuse in the Adult
Aaron Ettenberg, Ph.D. UC Santa Barbara Santa Barbara, CA	Dopamine involvement in Opiate and Stimulant Reinforcement

Appendix A Cont.

Principal Investigator	Title of Study
Sirine C. Fakra, Ph.D. Lawrence Berkeley National Laboratory Emeryville, CA	Evaluation of Industrial Hemp for Phytoremediation and Se Biofortification Applications
Christie Fowler, Ph.D. UC Irvine Irvine, CA	Mechanisms of Drug Reinforcement
Neil K. Garg, Ph.D. UCLA Los Angeles, CA	Optical and Electrochemical Detection of Tetrahydrocannabinol (THC) Towards a Functional Quantitative Breathalyzer
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Animal Models of Addiction: Preliminary Studies of Vaporized THC Self-Administration in a Rat Model
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments
Olivier George, Ph.D. The Scripps Research Institute La Jolla, CA	Preclinical Testing of CBD for the Treatment of Nicotine Dependence
Mark A. Geyer, Ph.D. Dept of Psychiatry, UCSD La Jolla, CA	Effects of Cannabidiol on Mania-relevant Locomotor and Investigatory Behavior
Alidad Ghiassi, M.D. Keck School of Medicine USC	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	Cannabinoid Regulation on Resting State Quantitative EEG, Sleep and Cognition
Judith Hellman, M.D. UCSF Dept of Anesthesia & Perioperative Care San Francisco, CA	Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury
Brook Henry, Ph.D. UC San Diego San Diego, CA	Effect of Cannabis Administration and Endocannabinoids on HIV Neuropathic Pain Study - Phase 2
Kanthi Hettiarachchi, Ph.D. SRI International Menlo Park, CA	Analysis of Controlled Substances
Kim D. Janda, Ph.D. The Scripps Research Institute La Jolla, CA	Vaccines for the Treatment of Opiate Addiction
Kim D. Janda, Ph.D. The Scripps Research Institute San Diego, CA	Immunopharmaco Therapy for Methamphetamine Addiction
Jay Keasling, Ph.D. Joint Bioenergy Institute Emeryville, CA	Engineering the Industrial Microbe Saccharomyces Cerevisiae for Biosyntheris of Cannabinoids

Appendix A Cont.

Principal Investigator	Title of Study
Sulggi A. Lee, MD, PhD UCSF San Francisco, CA	Effect of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Marie Lin, Ph.D. Lin-Zhi International Sunnyvale, CA	Lin-Zhi Immunoassay Development Study
Mallory Loflin, Ph.D. San Diego Veterans Affairs Medical Center San Diego, CA	Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

Principal Investigator	Title of Study
Stephen Mahler, Ph.D. UC Irvine Irvine, CA	Neural Circuits Underlying Motivation and Addiction
Robert Malenka, M.D. School of Medicine Stanford University Palo Alto, CA	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	Panel Approved Research Study
Faith Kennedy McDaniel, Ph.D. Koniku Inc. Berkeley, CA	Development of a Device that Detects Controlled Substances
Sara Mednick, Ph.D. UC Riverside Riverside, CA	The Effects of Zolpidem and Dextroamphetamine on Cognitive Performance
Lupe Mejorado, Ph.D. Alere San Diego, Inc. San Diego, CA	In Vitro Assay for the Synthetic Cannabinoids Belonging to JWH and Pinaca Family

Appendix A Cont.

Principal Investigator	Title of Study
Byung-Sook Moon ARK Freemont, CA	Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing
Stephen Morairty, Ph.D. SRI International Menlo Park, CA	Panel Approved Research Study
Heinz Moser, Ph.D. Novartis Institute Emeryville, CA	Synthesis and Optimization of Novel Therapeutics
Alysson Muotri, Ph.D. UC San Diego La Jolla, CA	The Impact of CBD/THC on Human Neurodevelopment
Fatta B. Nahab, M.D. 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)
David E. Olson, Ph.D. UC Davis Davis, CA	Chemical Modulation of Neural Plasticity, Learning and Memory
Lori Olson, M.S. SRI International Menlo Park, CA	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	The Effects of Developmental Cannabis Exposure on Brain and Behavioral Development in Rats
Mark Peterman, Ph.D. OndaVia Hayward, CA	Development of a Rapid and Field-Ready Heroin analysis Tool
Joy Phillips, Ph.D. San Diego State University San Diego, CA	Effect of Cannabis Inhalation on Respiratory Inflammation and Immune Function
Daniele Piomelli, Ph.D. UC Irvine Irvine, CA	1. Effect of Adolescent Cannabis Exposure in Adults Mice and Rats 2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids
Birgit Puschner, DVM, PhD UC Davis School of Veterinary Medicine Davis, CA	Analysis of Cannabinoids in Help Oil Veterinary Treats/Supplements Panel Approved Research Study
Richard Reznichek, M.D. Harbor-UCLA Los Angeles, CA	Panel Approved Research Study

Appendix A Cont.

Principal Investigator	Title of Study
Pietro Paolo Sanna, M.D. The Scripps Research Institute La Jolla, CA	Neural Substrates of Opiate-HIV Interactions
David Schubert, Ph.D. Salk Institute La Jolla, CA	The Identification of Neuroprotective Compounds in Cannabis
Philip Schwartz, Ph.D. Children's Hospital of Orange County Orange, CA	Effect of Receptor Activation on Human Neuron Stem Cell Function
Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA	Safety and Initial Efficacy of Lisdexamfetamine for Modifying the Behavioral Effects of Intravenous Methamphetamine in Humans
Mehrdad Shamloo, Ph.D. Stanford University Palo Alto, CA	Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases
Ivan Soltesz, Ph.D. Stanford University Stanford, CA	Investigating the Effect of Naturally-Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy

Principal Investigator	Title of Study
Matthew L. Springer, Ph.D. UCSF San Francisco, CA	Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol
Francesca Telese, Ph.D. UCSD La Jolla, CA	Epigenetic Regulation of Gene Expression in the Brain
Jeff Ubersax Demetrix, Inc. Emeryville, CA	Panel Approved Research Study
Rama Voladri, Ph.D. Codexis, Inc. Redwood City, CA	Transaminase Evolution Proposal for Genentech. Engineering ATA-P2-A07 for a synthesis of G03044577

Appendix A Cont.

Principal Investigator	Title of Study
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol
Joshua Woolley, MD, PhD UCSF VA Medical Ct. San Francisco, CA	Psilocybin-Assisted Group Therapy for Demoralization in Long-Term Aids Survivors
Matthew Worley, Ph.D. UCSD La Jolla, CA	Behavioral Economic Mechanisms of Prescription Opioid Addiction in Chronic Pain
Roya Yumul Cedars-Sinai Medical Ct. Los Angeles, CA	Intra-operative ketamine and methadone for laminectomy: effect on recovery, post-operative pain, and opioid requirements
Brandon Zipp, Ph.D. Vitality Biopharma, Inc. Los Angeles, CA	Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation

APPENDIX B

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

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes, Inc. Waltham, MA	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	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)
Alkermes, Inc. Waltham, MA	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)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes, Inc. Waltham, MA	A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder (ALK5461-218)
Alkermes, Inc. Waltham, MA	A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia (ALK3831-A303)
Alkermes, Inc. Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A306)
Alkermes, Inc. Waltham, MA	A Phase 1 Study to Evaluate the Effect of Multiple Doses of ALKS 3831 on QTc interval in Subjects with Schizophrenia (ALK3831-A109)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Alkermes, Inc. Waltham, MA	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)
Alkermes, Inc. Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A304)
Arbor Pharmaceuticals CRO: Rho Inc. Chapel Hill, NC	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)
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)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Botanix CRO: Premier Research Research Triangle Park, NC	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	Panel Approved Research Study
Corbus Pharmaceuticals Norwood, MA	A Multicenter, Randomized, Double-Bind, Placebo-Controlled Phase 3 Trial of Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis (JBT101-DM-002)
Corbus Pharmaceuticals Norwood, MA	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	Description or Title of Clinical Drug Trial Protocol
Flamel Ireland CRO: INC Research Austin, TX	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)
Grunenthal/Janssen CRO : inVentiv Cary, NC	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
GW Cambridge, UK	Panel Approved Research Study
INSYS Therapeutics Chandler, AZ	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)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
INSYS Therapeutics Chandler, AZ	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)
INSYS Therapeutics Chandler, AZ	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)
INSYS Therapeutics Chandler, AZ	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)
INSYS Therapeutics Chandler, AZ	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)

Sponsor	Description or Title of Clinical Drug Trial Protocol
INSYS Therapeutics Chandler, AZ	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	Panel Approved Research Study
NIH/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 Erythematosus (ALE09)

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Noven New York City, NY	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)
Pfizer CRO: ICON New York, NY	Panel Approved Research Study
Pfizer CRO: ICON New York, NY	Panel Approved Research Study
Purdue CRO: PRA Raleigh, NC	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)
Receptor Life Sciences CRO: WCCT Global Cypress, CA	A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Health Adult Participants (RC-2018/01)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Recro Pharma Malvern, PA	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)
Relmada Therapeutics, Inc. CRO: Syneos Health Cary, NC	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

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
West-Ward Pharmaceuticals CRO: Premier Research Columbus, OH	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	Randomized Trial of Ibudilast for Methamphetamine Dependence
Keith Heinzerling, M.D. UC Los Angeles Los Angeles, CA	Phase 1 Safety-Interaction Study of Pomaglumetad Methionil for Methamphetamine Use Disorder
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Varenicline for Methamphetamine Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine
NIDA/NSC/NIH Bethesda, MD	Phase 2, Multi-Center Trial of Lorcaserin for the Treatment of Cocaine Use Disorder (NIDA/VA CS #1033)

Appendix C Cont.

Investigator or Sponsor	Description or Title of Research Project
NIDA/NSC/NIH Bethesda, MD	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	Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT) (0051)
NIDA/CTN Rockville, MD	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 § 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.

§ 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.