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Research Advisory Panel of California

Special Report to the
California Legislature:

Resolution of the 2023-2024
Backlog of Applications



RAPC
RESEARCH ADVISORY
PANEL OF CALIFORNIA

RESEARCH ADVISORY PANEL OF CALIFORNIA

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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.

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LEGISLATIVE MANDATE

Pursuant to HEALTH AND SAFETY CODE SECTION 11480.5

California law, pursuant to Health and Safety Code Section 11480.5, requires the Research Advisory Panel of California (RAPC) to provide a one-time Special Report to the California Legislature that addresses the backlog of applications that occurred due to a procedural issue that affected RAPC in 2023 and 2024. RAPC is mandated to provide this report to the Legislature on or before January 1, 2026. The report must provide an update on the 2023-2024 backlog of applications that includes, at a minimum, the number of backlog applications that have been reviewed and how many are still pending Research Advisory Panel review.

All applications in the 2023-2024 backlog have been reviewed and the Panel has provided a response to each study in the backlog. This ***Special Report to the California Legislature: Resolution of the 2023-2024 Backlog of Applications*** provides details on the resolution of the 2023-2024 backlog and fulfills this mandate.

RESEARCH ADVISORY PANEL OF CALIFORNIA

2024 PANEL MEMBERS

RAPC consists of members appointed by (a) the University of California; (b) a statewide medical society designated by the Governor; (c) a private university designated by the Governor; (d) the California State Board of Pharmacy; (e) the Department of Public Health; (f) the Attorney General; and (g) the Governor. Members of RAPC serve without compensation. RAPC's staff consists of the Executive Officer, to carry out its day-to-day operations.

Jennifer Mitchell, PhD

Panel Chair

Professor of Neurology and Psychiatry and Behavioral Sciences, UCSF School of Medicine
Associate Chief of Staff for Research and Development, San Francisco Veterans Administration Medical Center (SFVAMC)

Appointed by the California State Governor

Martine D'Agostino, JD

Deputy Attorney General, State of California Office of the Attorney General, Oakland

Appointed by the California State Attorney General

Patrick R. Finley, PharmD, BCPP

Professor Emeritus, University of California, San Francisco (UCSF) School of Pharmacy

Appointed by the California State Board of Pharmacy

(Term ended on August 4, 2024)

James J. Gasper, PharmD, BCPP

Psychiatric and Substance Use Disorder Pharmacist, CA. Dept. of Health Care Services

Appointed by the California Department of Public Health

Boris Heifets, MD, PhD

Associate Professor of Anesthesiology, Perioperative and Pain Medicine

And by courtesy, Psychiatry and Behavioral Sciences, Stanford University School of Medicine

Appointed by Stanford University

Kelly C. Lee, PharmD, MAS, BCPP, FCCP, FASHP

Professor of Clinical Pharmacy, Associate Dean for Assessment and Accreditation, and
Director, PGY2 Residency in Psychiatric Pharmacy, University of California, San Diego

Appointed by the California State Board of Pharmacy

(Term started on December 5, 2024)

Daniele Piomelli, PhD

Distinguished Professor, University of California, Irvine School of Medicine Director, Center for the Study of Cannabis

Appointed by the University of California

(Term started on July 16, 2024)

Cyrus Rangan, MD, FAAP, FACMT

Toxicologist and Assistant Deputy Director, Center for Healthy Communities California Department of Public Health

Designee for Public Health Officer Tomás Aragón, MD, DrPH

Term started on August 6, 2024)

RAPC Staff

Tanveer Khan, PharmD

Executive Officer

Appointed by the California State Attorney General

SUMMARY OF ACTIVITIES

RESOLUTION OF THE 2023-2024 BACKLOG OF APPLICATIONS

A procedural issue affecting Research Advisory Panel of California (RAPC) meetings in 2023 and 2024 resulted in a backlog of 67 studies requesting review and approval. This “backlog” included all studies that submitted applications for a posted Panel meeting date occurring prior to June 15, 2024. That procedural issue was resolved with the passage of [Assembly Bill 2841](#) on July 18, 2024. This bill authorized the Research Advisory Panel to hold closed sessions for the purpose of discussing, reviewing, and approving research projects that contain sensitive and confidential information, including trade secrets, intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law. The 2023-2024 backlog has been resolved, and the following summary provides details on the resolution.

A Special Session Panel meeting took place on July 19, 2024, to address the 2023-2024 backlog. A total of 63 out of the 67 studies in the 2023-2024 backlog had completed their applications and were reviewed at the July 19, 2024 panel meeting. The remaining four out of the 67 applications in the 2023-2024 backlog were sent communications with guidance on completing their applications.

The 63 applications that were reviewed at the July 19, 2024 Panel meeting included 43 new studies and 20 amended studies. RAPC approved 32 of the new studies and all 20 of the amended studies (a total of 52 studies) during this meeting. Approval letters were issued to these 52 studies within seven days after the meeting. The remaining 11 out of the 63 applications that were not approved during the July 19, 2024 meeting were sent response letters. In these response letters, three studies were notified that they did not fit the statutory requirements for RAPC review and were exempt from review. Five studies were asked to provide clarifications to their applications. These studies provided the requested clarifications, and RAPC approved them at the August 16, 2024 Panel meeting. The three remaining studies either withdrew their applications or did not respond to Panel communications and were not approvable.

The four studies that did not complete their applications in time for the July 19, 2024 Panel meeting and received communications on completing their applications responded as follows: Three studies never completed their applications, did not respond to Panel communications, and were therefore not approvable. The remaining study completed its application, was reviewed at the August 16, 2024 Panel meeting, and was issued a response letter with guidance on submitting a new, revised application. The study submitted the new application in 2025, and it was approved by the Panel.

In conclusion, all 67 studies in the 2023-2024 backlog of applications awaiting RAPC review and approval have been addressed. All studies were either reviewed and received an approval letter or were sent a response within six weeks after the passage of Assembly Bill 2841. Please see Table 1 for listings of new applications approved by RAPC, and Table 2 for listings of amended applications approved by RAPC. The 2023-2024 backlog of applications is completely resolved.

TABLE I
2023-2024 BACKLOG OF APPLICATIONS RESOLUTION
NEW RESEARCH STUDIES APPROVED

ACADEMIC AND INDEPENDENT HUMAN RESEARCH STUDIES

Ausaf Bari, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Electrophysiological Correlates of Opioid Use and its Associated Changes In Affect Using Direct Invasive Human Neuronal Recordings

Anya Bershad, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Tolerability of MDMA in Schizophrenia

Robin Carhart-Harris, PhD | University of California, San Francisco | San Francisco, CA

2 x 2 Factorial, Double-Blind, Randomized Study of ‘Set and Setting’: A Translational Study in Healthy Volunteers

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Effects of Smoked Cannabis on Pain and Opioid Withdrawal among People on Long-term Opioid Treatment

Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA

Sex- and Age-Dependent Effects of Smoked and Oral Delta-9-THC

Alison Giovanelli, PhD | University of California, San Francisco | San Francisco, CA

Impacts of THC Potency of Cannabis Concentrates and THC Metabolism on Cognitive Impairment in Young Adults

Stephen Marder, MD | Veteran’s Administration. Los Angeles | Los Angeles, CA

A Randomized, Double-Blind, Single-Site Phase II 2-Arm Study to Compare the Safety and Preliminary Efficacy of Manualized MDMA-Assisted Therapy to Low Dose D-Amphetamine Assisted Therapy in Veterans for the Treatment of Moderate to Severe PTSD

Leslie Morland, PsyD | Veteran's Administration San Diego | San Diego, CA

MDMA-Assisted Massed Prolonged Exposure for PTSD

Marissa Raymond-Flesch, MD, MPH. | University of California, San Francisco | San Francisco, CA

Study of Psilocybin for the Treatment of Anorexia Nervosa in Young Adults

Gideon St. Helen, PhD | University of California, San Francisco | San Francisco, CA

Understanding the Clinical Pharmacology of Marijuana-Tobacco Co-Administration

Michael Silver, PhD | University of California, Berkeley | Berkeley, CA

Investigating the Persisting Effects of a Single Dose of Psilocybin on Cognition, Predictive Coding, and Affect in Healthy Older Adults (BCSP02)

Patricia Suppes, MD, PhD | Veteran's Admin. Palo Alto/Stanford University| Palo Alto, CA

A Randomized Trial to Compare MDMA-Assisted Therapy (MDMA-AT) versus Cognitive Processing Therapy (CPT), a VA Standard of care for PTSD, for the Treatment of Severe Post-Traumatic Stress Disorder

CLINICAL DRUG TRIAL RESEARCH STUDIES**Relmada Therapeutics, Inc. | Coral Gables, FL**

A Randomized, Double-Blind Placebo-Controlled Trial of REL-1017 as an Adjunctive Treatment for Major Depressive Disorder (The RELIGHT Study)

Usona Institute | CRO: Worldwide Clinical Trials | Madison, WI

A Phase 3, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Psilocybin in Adults with Major Depressive Disorder

Hound Labs, Inc | Fremont, CA

Study to Evaluate the Aging Process of Hound Cannabis Breathalyzer: Collect + Send Cartridges

Hound Labs, Inc | Fremont, CA

Study to Evaluate Performance of the Hound Cannabis Breathalyzer - On Demand

Lundquist Institute for Biomedical Innovation | Torrance, CA

Pragmatic Trial of Psilocybin Therapy in Palliative Care (PT2PC): A Multicenter Triple-blind Phase 2 Randomized Controlled Trial of Psilocybin Therapy for Demoralized Adults Near the End of Life

Beckley Psytech Ltd. | Worldwide Clinical Trials | Nottingham, UK

A Quadruple Masked, Dose-Finding Study to Evaluate the Efficacy and Safety of Intranasal BPL-003 in Patients with Treatment-Resistant Depression. CORE Study

SUBSTANCE USE DISORDER RESEARCH STUDIES**Ziva Cooper, PhD | University of California, Los Angeles | Los Angeles, CA**

Safety Profile of 25 mg Psilocybin in Individuals with Cocaine Use Disorder

Ethan Cowan, MD, MS | Icahn Mount Sinai School of Medicine | New York, NY

Safety and Efficacy of High Dose BUP Induction in Fentanyl Positive Emergency Department Patients

Yale University and NIDA | New Haven, CT

Office-Based Methadone Versus Buprenorphine to Address Retention in Medication for Opioid Use Disorder Treatment - A Randomized Pragmatic Hybrid Effectiveness/Implementation Trial

Yih-ing Hser, PhD | University of California, Los Angeles/NIDA Sciences | Los Angeles, CA

Randomized Controlled Pilot Trial of Extended-Buprenorphine vs. Sublingual Buprenorphine-naloxone in Rural Settings (RXR)

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

Randomized, Placebo-Controlled, Multi-Site Trial of Extended-Release Naltrexone Injection/Bupropion XL Tablets in the Treatment of Methamphetamine Use Disorder

NON-HUMAN RESEARCH STUDIES

Ryan Baxter, PhD | University of California, Merced | Merced, CA

Light Control and Oxidation Potential of Cannabinoids

Kevin Beier, PhD | University of California, Irvine | Irvine, CA

Reversing Maladaptive Plasticity Using Psilocybin

Jerel Fields, PhD | University of California, San Diego | La Jolla, CA

Cannabis and Pathogenic Mechanisms Influencing Blood Brain Barrier Function in HIV

Deron Herr, PhD | Sanford Benham Prebys Medical Discovery Institute | La Jolla, CA

Biosynthesis and Biological Mechanism of Minor Cannabinoids

Jaime Inman, PhD | Lawrence Berkeley National Laboratory | Berkeley, CA

Contribution of Genetic Factors to Individual Differences in Anxiety in Response to the Cannabinoids THC and CBD

Christina Kim, PhD | University of California, Davis | Davis, CA

Brainwide Molecular Profiling of Activated Neuronal Circuits

David E. Krantz, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Serotonergic Signaling in Drosophila

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

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

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

Anca M. Pasca, MD | Stanford University | Palo Alto, CA
Exploring the Potential Role of Psychedelics in the Treatment of the Psychiatric Sequelae of 22q11.2 Deletion Syndrome

Daniele Piomelli, PhD | University of California, Irvine | Irvine, CA
A Translational Study on the Short- and Long-term Effects of High Dose Delta-9-tetrahydrocannabinol (THC)

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

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

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

TABLE 2

2023-2024 BACKLOG OF APPLICATIONS RESOLUTION

AMENDED RESEARCH STUDIES APPROVED

Compass Pathfinder Limited | CRO: ICON plc | Cheshire, UK

A Phase III, Multicentre, Randomised, Double-Blind, Controlled Study to Investigate the Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants with Treatment-Resistant Depression (COMP 006)

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

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

Adam Halberstadt, PhD | University of California, San Diego | La Jolla, CA

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

Timothy Furnish, MD | University of California, San Diego | San Diego, CA

Behavioral and Neural Mechanisms Supporting Psilocybin Assisted Therapy for Phantom Limb Pain

Frank Kochinke, PhD | LC Pharmaceuticals, LLC | San Diego, CA

Sustained Delivery of Psilocybin, Psilocin, DMT, LSD, MDMA, THC, and 5-MEO-DMT, with Synthesis of APIs

Edythe London, PhD | University of California, Los Angeles | Los Angeles, CA

Cannabidiol Effects on Craving and Relapse Prevention in Opioid Use Disorder. (Previously: Cannabidiol as Adjunctive Treatment for Opioid Use Disorder)

Leslie Morland, PsyD | Veteran's Admin. San Diego Healthcare System | San Diego, CA

MDMA-Assisted Brief Cognitive Behavioral Conjoint Therapy for PTSD

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

Emergency Department-Initiated Buprenorphine Validation Trial

Relmada Therapeutics, Inc. | Coral Gables, FL

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

Trisha Suppes, MD, PhD | Veteran's Admin. Palo Alto Health Care System | Palo Alto, CA

The Safety and Efficacy of Psilocybin in Participants with Severe Treatment-Resistant Depression (P-TRD)

Skye Bioscience, Inc. | San Diego, CA

A Phase 2, Double-Masked, Randomized, Vehicle-Controlled, Dose-Response Study Assessing the Safety and Ocular Hypotensive Efficacy of Two Concentrations of SBI-100 Ophthalmic Emulsion in Patients with Elevated Intraocular Pressure

Kay Tye, PhD | Salk Institute | La Jolla, CA

The Cellular Basis of Motivated Behaviors in Health and Disease: Assessment of Acute and Persistent Changes in Behavioral and Neural Correlates of Emotional Valence Processing Produced by Psilocybin

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

Psilocybin - Assisted Cognitive Behavioral Therapy for Major Depressive Disorder

Scott A. Wilke, MD, PhD | University of California, Los Angeles | Los Angeles, CA

Psychostimulant Augmentation of Repetitive TMS (rTMS) for the Treatment of Major Depressive Disorder: A Randomized, Placebo-Controlled Clinical Trial

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

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

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

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

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

A Double-Blinded, Active Placebo-Controlled, Randomized Trial Examining the Feasibility and Preliminary Efficacy of Psilocybin Therapy for People with Chronic Low Back Pain

Joshua Woolley, MD, PhD | University of California, San Francisco | San Francisco, CA

An Open-Label Pilot Study Examining the Feasibility, Safety, and Effectiveness of Psilocybin Therapy for Depression in Bipolar II Disorder

Yale University| US Dept. of Veteran's Affairs | West Haven, CT

Proof of Concept Trial of Cannabis Derivatives in Neuropathic Pain (CANalgesia)

Fadel Zeidan, PhD | University of California, San Diego | La Jolla, CA

Brain Mechanisms of Cannabis-Based Analgesia

APPENDIX A

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

Health and Safety Code Section 11213 - Persons and Research Using Controlled Substances

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and Section 11481. Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Health and Safety Code Section 11480 - Research Advisory Panel

- (a) The Legislature finds that there is a need to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects.
- (b) There is a Research Advisory Panel that consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, the State Public Health Officers, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this state who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the panel. Members of the panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.
- (c) The Research Advisory Panel shall appoint two special members to the Research Advisory Panel, who shall serve at the pleasure of the Research Advisory Panel only during the period Article 6 (commencing with Section 11260) of Chapter 5 remains effective. The additional members shall be physicians and surgeons, and who are board certified in oncology, ophthalmology, or psychiatry.

- (d) The panel shall annually select a chairperson from among its members.
- (e) The panel may hold hearings on, and in other ways study, research projects concerning cannabis or hallucinogenic drugs in this state. Members of the panel shall serve without compensation but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.
- (f) The panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of cannabis or hallucinogenic drugs and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of cannabis pursuant to Section 11478.
- (g) The panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of cannabis to the Attorney General.
- (h) The panel shall report annually to the Legislature and the Governor those research projects approved by the panel, the nature of each research project, and, where available, the conclusions of the research project.

Health and Safety Code Section 11481 - Research Advisory Panel

The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

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

Health and Safety Code Section 11480.5 - Research Advisory Panel as Multimember Advisory Body; Report to Legislature on Backlog of Applications

- (a) The Research Advisory Panel shall be considered a multimember advisory body solely for the purposes of Section 11123.5 of the Government Code.
- (b) The panel shall provide a report to the Legislature on or before January 1, 2026, that provides an update on the backlog of applications that includes, at minimum, the number of backlog applications that have been reviewed and how many are still pending review.
- (c) This section shall remain in effect only until January 1, 2027, and as of that date is repealed.