California Health and Safety Code §11480.1

§11480.1.

(a) The panel shall review and may approve research projects to be conducted in this state that would require the administration of Schedule I or Schedule II controlled substances.

(b) The panel shall inform the Attorney General of the head of the approved research projects that are entitled to receive quantities of cannabis pursuant to Section 11478.

(c) The panel may expedite the review of completed and timely applications for research projects involving the administration of Schedule I, Schedule II, or both, controlled substances that comply with federal law and include all of the following:

(1) For all research projects, proof of independent peer review of the study for scientific merit and rigor by the National Institutes of Health, the United States Department of Defense, the Heffter Research Institute, the United States National Science Foundation, or a comparable group within an institutional setting that has previous experience with research or grant review.

(2) For all research projects, if otherwise required by law, one of the following:

(A) A Schedule I or II research registration issued by the United States Drug Enforcement Administration.

(B) An approval from the United States Drug Enforcement Administration for a research registration that is conditional on the approval of the panel.

(C) A copy of the application for a research registration submitted to the United States Drug Enforcement Administration, accompanied by a written acknowledgment of receipt of the application.

(D) Other evidence of authorization to conduct the research project pursuant to the federal Controlled Substances Act.

(3) For research projects involving human subjects, if approval by the United States Food and Drug Administration of an investigational new drug application is otherwise required by law, one of the following:

(A) A letter from the United States Food and Drug Administration approving the application for an investigational new drug.

(B) A letter from the United States Food and Drug Administration indicating that the study may proceed.

(C) Documentation that the 30-day statutory period for the United States Food and Drug Administration to respond to a project's submission of an application for approval of an investigational new drug has expired.

(D) A signed copy of the United States Food and Drug Administration Investigational New Drug Application.

(4) (A) For research projects involving human subjects, an approval letter from an institutional review board established in accordance with federal law, including, but not limited to, Part 46 of Title 45 of the Code of Federal Regulations, demonstrating that the board's evaluation of the underlying research protocol has considered relevant federal and state laws regarding the use of human subjects, including, but not limited to, the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20) and laws governing research involving inmates, as described in Title 2.1 (commencing with Section 3500) of Part 3 of the Penal Code, the Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code), and laws governing birth and death certificates, as described in Part 1 (commencing with Section 102100) of Division 102. A letter submitted pursuant to this paragraph may indicate approval by the board conditioned upon the approval of the panel.

(B) For research projects involving animal subjects, an approval letter from an institutional animal care and use committee (IACUC) established pursuant to federal law demonstrating that the IACUC has considered relevant federal and state laws regarding for the use of live, vertebrate animals in the research project, and their humane treatment.

(d) Applications for research projects that do not satisfy the criteria set forth in subdivision (c) shall be reviewed pursuant to the standard review process and approved by a review of the full panel. The panel's process for conducting expedited review and its criteria for approving research projects described in subdivision (c) shall be published on the panel's internet website.

(e) Upon receiving a research project application that satisfies the criteria in subdivision (c), the panel chairperson, in consultation with the panel's executive officer, may assign two or more individual panel members to conduct an expedited review of eligible research applications and deputize those panel members to approve those applications on behalf of the panel without the need for a full panel vote at a regularly scheduled meeting of the panel. Assigned panel

members shall have the authority to approve research project applications eligible for expedited review that also satisfy the criteria for approval published on the panel's internet website, pursuant to subdivision (d). Individual panel members are additionally authorized to communicate and consult asynchronously with other individual panel members with complementary core competencies outside of panel meetings in order to conduct their individual reviews. Panel members assigned to conduct an expedited review pursuant to this subdivision are not a state body under the Bagley-Keene Open Meeting Act. Panel members shall notify the panel's chairperson and executive officer of their decision to approve or withhold approval of the eligible research applications assigned for their review.

(f) This section shall remain in effect only until January 1, 2028, and as of that date is repealed.