

Provention Bio Compliance Program

Our mission to seek out autoimmunity early to intercept and prevent debilitating and life-threatening diseases cannot be met without total commitment to compliance in all areas of our business. Provention Bio, Inc. (“PRVB”) proactively implements an effective compliance program designed to meet external requirements applying high ethical, moral and legal principles in every aspect of its business conduct.

PRVB’s compliance program is a central component of how business is conducted and is based on the “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General (“OIG”), U.S. Department of Health and Human Services (“DHHS”), and the “Code on Interactions with Health Care Professionals” published by the Pharmaceutical Research and Manufacturers of America (“PhRMA Code”). The fundamental elements of our compliance program are outlined below.

Compliance Leadership

PRVB has identified an individual who is responsible for developing, operating and monitoring the compliance program. This person reports to the Chief Legal Officer and has direct access to the Chief Executive Officer and Board of Directors regarding all compliance concerns.

Compliance Committee

PRVB has established a Compliance Committee consisting of the top leaders from all company business areas and support functions. The committee is responsible for advising and supporting the Compliance Officer in the implementation and oversight of the compliance program. The Compliance Officer periodically provides reports on the state of PRVB’s compliance program to the Audit Committee of the Board of Directors.

Code of Business Conduct and Ethics and Documented Policies and Procedures

PRVB has implemented a Code of Business Conduct and Ethics (the “Code”) that serves as a guide for each of the Company’s directors, officers and employees to follow. This Code describes certain ethical principles that the Company has established for the conduct of its business, and outlines certain key legal requirements of which the Company’s directors, officers and employees must be generally aware and with which they must comply. This Code is available on its website at www.proventionbio.com.

In addition to this Code, PRVB has documented policies and procedures that address the Company’s expectations regarding adherence to all applicable laws and regulations. These policies and procedures address the risk areas identified in the OIG guidance and the PhRMA code, as well as other areas specific to PRVB’s activities.

Training

PRVB is dedicated to an ongoing training and education program for its employees with regard to their legal and ethical obligations. PRVB trains its employees on its Code of Business Conduct and Ethics, PRVB policies and procedures, and specific risk areas related to each employee’s responsibilities. The training program is subject to review and modification as deemed appropriate by the company.

Communication

PRVB encourages free flow of concerns from employees with regard to its business activities. All employees have access to report potential instances of fraud and abuse or other instances of potential violation of law, regulations or company policy and procedures. These reports may be submitted through their Management, Human Resources, Compliance, or Legal. Potential violation of fraud and abuse or other instances of potential violation of law, regulations or Company policy and procedures involving directors or executive officers must be submitted to the Audit Committee of the Board of Directors. In addition, PRVB has established a communication channel to report potential violations of laws, policies and procedures. If desired, the individual may submit reports anonymously.

Reports can be submitted anonymously by a toll-free call to **1-844-449-7503**.

PRVB does not tolerate any form of retaliation against individuals who report in good faith potentially improper, unethical or illegal conduct.

Auditing and Monitoring

PRVB's compliance program includes ongoing efforts to assess, evaluate, monitor, and audit compliance with the Company's policies and procedures. The results of these activities are reported to management to help guide the risk assessment process.

Corrective Action

PRVB has an established disciplinary process for those employees who violate the law, regulations or Company policy and procedures. The company will investigate the matter based on the nature of the violation and consider discipline to address the violation and prevent or correct where necessary. In addition to imposing appropriate disciplinary action, the Company also assesses whether a violation may be due in part to gaps in PRVB's policies, procedures, training, business practices and other controls. If so, the Company is committed to implementing corrective and preventative measures to enhance its controls to prevent further violations.

Annual Declaration of Compliance for Purposes of California Health & Safety Code Sections 119400-119402

PRVB has developed a Comprehensive Compliance Program ("CCP") in accordance with the requirements of California Health & Safety Code sections 119400-119402. As of January 31, 2023, PRVB hereby declares in good faith that it is, in all material respects, in compliance with its CCP and the requirements of California Health & Safety Code §§ 119400-119402. PRVB has developed and implemented elements of its CCP to address certain issues uniquely raised by the California law. In addition, compliance is a dynamic concept and, therefore, PRVB periodically assesses the effectiveness of its CCP and may modify aspects of the CCP to enhance it. For a copy of this declaration and a description of PRVB's CCP, email compliance@proventionbio.com

In accordance with California Health and Safety Code section 119402(d)(1), PRVB has established an annual limit of \$3,500 for spending on promotional items and activities provided to a health care professional licensed in California. For items and activities that are not prohibited, such items generally

are provided to physicians and certain other health care professionals in order to facilitate an educational or scientific discussion about the Company's products, the Company's research and development efforts, and other health care-related issues. PRVB's limit also includes educational items provided to a physician (such as a medical textbook) that are intended to benefit patient care. Additionally, pursuant to California Health & Safety Code § 119402(d)(2) and (3), drug samples given to healthcare professionals intended for free distribution to patients, PRVB financial support for continuing medical education forums, financial support for health educational scholarships, and fair market value payments made for legitimate services provided by a health care medical professional to PRVB, including but not limited to consulting, have also been excluded from the spending limit. This stated limit is not a goal, but a maximum that the Company sets for itself as a limitation. In most cases, the amounts actually spent are significantly less than the maximum amount set by this limitation. PRVB may change this spending limit upon review at the discretion of the Company.

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