

January, 2026.-

STATEMENT OF COMPLIANCE WITH GOOD CLINICAL PRACTICES

The Scientific Ethics Committee of Health Sciences of the *Pontificia Universidad Católica de Chile* (CEC Salud UC) is organized, acts and issues its rulings in full compliance with the Declaration of Helsinki (1964 and its subsequent amendments, last updated in 2024), the Good Clinical Practices (GCP) Standards established by the World Health Organization (WHO), 1996, the guidelines of the International Council for Harmonisation (ICH - Harmonised Tripartite Guidelines for Good Clinical Practice (1996 and subsequent amendments, last updated 2025), respecting current national laws related to the regulation of scientific research in Chile and those of the Ministry of Health of the Government of Chile.

The Committee complies with National Laws: Decree with Force of Law 725 (Health Code), Supreme Decree No. 3/2010 (Approves regulations of the national control system for pharmaceutical products for human use) Law 20.120 (On scientific research in human beings, their genome, and prohibition of human cloning), Law 20.854, which regulates the rights and duties of individuals in relation to actions linked to their health care; Law 19628 (Law on the Protection of Private Life); Law 21719 (Regulates the Protection and Processing of Personal Data and Creates the Personal Data Protection Agency), Law 21.278 (which amends the health code to regulate the execution of studies and clinical trials, aimed at obtaining pharmaceutical products and medical devices). Technical Standard Number 57 of June 4th, 2001, and all Regulations on the Execution of Clinical Trials that use Pharmaceutical Products in Human Beings such as Resolution 5161 EXEMPT/2017 and Resolution 5174/2017 of the Ministry of Health of the Government of Chile. As well as the Guideline for Good Clinical Practices prepared by the National Medicines Agency Department of the Public Health Institute (Exempt Resolution No. 460 dated January 20th, 2015, for the fight against diseases that cause a health alert) and Law 20.850 (Creates a financial protection system for high-cost diagnoses and treatments and pays posthumous tribute to Mr. Luis Ricarte Soto Gallegos), Exempt Resolution No. 00173 dated January 29th, 2025, which approves the “Guide of general considerations for clinical studies” prepared by the National Medicines Agency Department of the Public Health Institute and complying with the institutional regulations of the *Pontificia Universidad Católica de Chile*.

Ivonne Vargas Celis
IVONNE VARGAS CELIS
President

Scientific Ethics Committee of Health Sciences
Pontificia Universidad Católica de Chile

