FACULTY OF HEALTH
Health Research Ethics Committee

APPROVAL MINUTES No. (011-2025)

Project: **"RANDOMIZED CLINICAL TRIAL TO EVALUATE THE EFFECT OF CONSUMING RETINOL-FORTIFIED SUGAR ON PLASMA LEVELS IN CHILDREN AGED 3 TO 5 YEARS"**

Principal Investigator: **ADALBERTO SÁNCHEZ GÓMEZ**
Other Investigators: **MARÍA VICTORIA BENJUMEA RINCÓN - CRISTIAN DAVID SANTA ESCOBAR - JUAN PABLO RESTREPO JIMÉNEZ**

Internal Code: (051-025)

Date Issued:

DAY	MONTH	YEAR
23	7	2025

The Council of the School of Health Sciences at the Universidad del Valle has established the Health Research Ethics Committee (**CEIS**), which is governed by Resolution 8430 of 1993 "establishing the scientific, technical, and administrative standards for health research" issued by the Ministry of Health, and in the absence of a specific regulation for ethics committees that do not review protocols involving drugs, it will adhere to Resolution 2378 of 2008 "Adopting Good Clinical Practices for institutions conducting research with drugs in human subjects" issued by the Ministry of Social Protection, where necessary, the principles of the World Medical Association's Declaration of Helsinki, as last revised in 2013, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS–WHO, 2016), and the Code of Federal Regulations, Title 45, Part 46, for the protection of participants, issued by the U.S. Department of Health and Human Services' National Institutes of Health in 2000.

This Committee **certifies that**:

1. Its members reviewed the following **documents** related to this project:

X	Research Protocol
X	Data Collection Instruments
X	Informed Consent Form
X	Documents Requested by the CEIS

2. According to the risk categories established in Article 11 of Ministry of Health Resolution No. 008430 of 1993, this study has **the** following **Risk Classification:**

X	**Risk greater than the minimum**

3. The CEIS states that it reviewed:

a. That the **measures** to be taken to protect participants are adequate.
b. The method for obtaining informed **consent** from study participants is appropriate.
c. Participation will be voluntary.

4. The CEIS will report the following non-compliance issues to the Office of the Associate Dean for Research:

a. Any failure by the researchers to comply with the Committee's requests.
b. Any suspension or revocation of approval by the Committee.

c. Injuries to participants.

d. Unforeseen problems involving risks to participants or other individuals.

e. Any situation requiring resolution outside the Committee.

5. This project has been approved for a period of one (1) year from the date of issuance; if the project duration exceeds one year, a renewal of the approval must be requested once this period has elapsed.
This project must submit a progress report within six (6) months from the date of issuance, attaching the progress report form and the required documents.

6. The **principal investigator must** inform the Committee of:

a. Any changes proposed to this project (amendments). These changes may not be implemented without the Committee's review and approval, except when necessary to eliminate imminent hazards to participants.

b. Any unforeseen problems involving risks to participants or others.

c. Any serious adverse event within the first 24 hours of its occurrence, to the secretary and the chair.

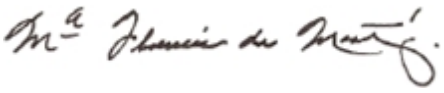
d. Any new information regarding the study that may affect the risk-benefit ratio for participants.

e. Any decision made by other ethics committees.

f. Premature termination or suspension of the project, explaining the reason for it.

7. The principal investigator must submit the final report upon completion of the project.

Signature:



Name: **MARÍA FLORENCIA VELASCO DE MARTÍNEZ**
Title: VICE PRESIDENT Phone: (602) 518-5677