NATIONAL POLYTECHNIC INSTITUTE
SUPERIOR SCHOOL OF MEDICINE
GRADUATE STUDIES AND RESEARCH SECTION

COMITE DE ETICA EN INVESTIGACIÓN

Informed consent for participants

Institution: Instituto Politécnico Nacional
Unit: Interdisciplinary Center for Health Sciences - Santo Tomás Unit
Program: Master in Psychological Intervention
LGC: Chronic-Degenerative Diseases
Title of Research: Immunogenicity induced by COVID-19 vaccines in Mexican population: mRNA expression for IgG anti-spike. Address: Av. De los Maestros s/n Col. Santo Tomás. Alcaldía Miguel Hidalgo. C.P. 11340, CDMX
Principal Investigator: Dr. Nadia Mabel Pérez Vielma. Tel. 55 2058 3053
Student responsible: Claudia Mariana Andrade Torres Tel. 55 3453 5322
Mexico City, CDMX, July 10, 2021

The Centro Interdisciplinario de Ciencias de la Salud Unidad Santo Tomás of the Instituto Politécnico Nacional; through the Studies and Postgraduate Section of this same unit, support the realization of the following protocol of:

Immunogenicity induced by vaccines against COVID-19 in Mexican population: expression of mRNA for IgG anti-spike.

Active cases of COVID-19 as well as asymptomatic carriers continue to increase in our country, despite immunization strategies through vaccines. This represents a serious public health problem that impacts all sectors of the population and public life.
Therefore, the present study focuses on identifying the molecular mechanisms by which a person who has received the complete vaccination schedule is not exempt from contracting the disease later.

Voluntary Acceptance

I _____, declare under protest to tell the truth and endorsing with my signature at the end of this document, that I am of legal age and I give my consent to participate in the research entitled "Immunogenicity induced by vaccines against COVID-19 in the Mexican population: mRNA expression for anti-spike IgG" committing to cooperate with the process described below in the following points:

a. My participation is completely voluntary and very important; however, I can refuse even if I agree to participate; having the absolute freedom to leave the study without any problem or consequence.

b. The main purpose of the research is to identify the molecular mechanisms by which a person who has received a complete COVID-19 vaccination schedule is not exempt from contracting the disease later.

c. It has been explained to me that I will not be given any financial compensation for my participation in this research; at the same time, it will not have any cost for me.

d. It has been explained to me that for this research it is important to know my general state of health, as well as demographic data and personal pathological history (chronic degenerative diseases, history of COVID-19...) that will be collected through a clinical history applied by specialized personnel, which does not represent any risk to my health.

e. It has been explained to me that for this research it is important to measure the levels of expression of the mRNA for anti-spike IgG in order to obtain knowledge at a biological level to determine the molecular mechanisms of COVID-19 contagion, which will allow avoiding contagion both in subjects of first contact and in those who have a history of SARS-CoV-2 disease. This measurement will be carried out by puncturing a vein in the arm to obtain blood samples (3 ml per occasion), at 30, 60 and 120 days after completing the COVID-19 vaccination schedule. This procedure will be carried out by specialized personnel who will use a purple vacutainer tube to take blood samples. The tRNA will be extracted and later used to evaluate gene expression in terms of the increase in the number of copies using the real-time PCR technique. This venipuncture involves minimal risk and will cause the expected discomfort from taking a blood sample. I have been informed that the analysis of gene expression has no repercussions for me or my relatives.

f. I have been informed that the genetic samples will be stored at -80 °C for the duration of the research. The sample can be destroyed at my request. I have also been informed that the samples become unusable after one year.

g. I am aware that the aforementioned venipuncture procedure will be carried out in three stages, a first stage 30 days after having a complete COVID-19 vaccination schedule, a

second stage 30 days after the first sample is taken, and a final stage 60 days after the second sample is taken.

h. I am aware that this research will have minimal risk, so it is not considered to be dangerous for my health.

i. I have been informed that the following research protocol is approved by the Research Ethics Committee for its implementation.

j. I have been informed that all information obtained during my participation in the research is completely confidential. Likewise, it will be destroyed as soon as I request it if I so require or if I decide to leave the process before the three required blood samples are taken. All information will be for research purposes only; the information provided by me will be processed statistically and is completely anonymous.

If I require additional information, have questions or concerns about the research; before, during or after participating, I can request it with absolute freedom and confidence from the social service intern Claudia Mariana Andrade Torres at tel. 55 3453 5322 and from the researcher in charge Dr. Nadia Mabel Pérez Vielma at tel. 55 2058 3053.

NAME, SIGNATURE AND ADDRESS OF THE PARTICIPANT	NAME AND SIGNATURE OF THE RESEARCHER

NAME, SIGNATURE AND ADDRESS OF WITNESS 1	NAME, SIGNATURE AND ADDRESS OF WITNESS 2

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