Universidad Veracruzana

VERACRUZ UNIVERSITY
INSTITUTO DE INVESTIGACIONES MEDICO BIOLOGICAS
ITURBIDE S/N ENTRE CARMEN SERDAN Y 20 DE NOVIEMBRE
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Instituto de Investigaciones Médico-Biológicas

INFORMED CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:
"Impact of diet on fatty liver."

Researchers: Ana Delfina Cano Contreras, MD.
José María Remes Troche, MD.
VENUE where the study will be carried out: Universidad Veracruzana, Instituto De Investigaciones Medico-Biologicas (Medical-Biological Research Institute)

Name of patient or legal representative: _____
You are being invited to participate in this medical research study. Before deciding whether or not to participate, you should know and understand each of the following sections. This process is known as **Informed Consent**. Feel free to ask questions about any aspect that will help you clarify your doubts about it. Once you have understood the study and if you wish to participate, then you will be asked to sign this consent form, a signed and dated copy of which will be given to you.

1. JUSTIFICATION FOR THE STUDY:
Non-Alcoholic Fatty Liver Disease (NAFLD), also known as **FATTY LIVER**, affects the liver of those who do not consume large amounts of alcohol and is frequently associated with diabetes, high blood pressure, obesity and high fats. This is a silent disease, since most of the time it does not give symptoms until it is in advanced stages. Most of those affected will store fat in their liver permanently, unless corrective measures are taken; but the most worrisome thing is that in some cases this disease can progress to liver cirrhosis and liver cancer. Currently, lifestyle modifications (dietary changes and physical activity) are the best therapeutic intervention, although some drugs are under study. Thus, our study will investigate the pathophysiological and genetic basis of this disease in a Mexican population.

2. OBJECTIVE OF THE STUDY:
To analyze the impact of diet and antioxidant use on the natural history of fatty liver disease and fibrosis.

3. PROTOCOL AND PROCEDURES:
If you agree to participate in the study, you will attend the first appointment for the initial *FibroScan*, then you will receive nutritional counseling, where a medical history will be taken, and you will be given a diet. Follow-up with *FibroScan will be* done *at* 3 and 6 months. Complementary clinical questionnaires related to physical activity, adverse experiences and anxiety and depression will be applied. *FibroScan* results will be sent to your email.

4. BENEFITS OF THE STUDY:

This study will allow us to obtain results with the aim of helping to answer scientific questions about NASH, which may help in the prevention and development of new therapeutic interventions in the Mexican population.

5. RISKS ASSOCIATED WITH THE STUDY:

If you agree to participate in this study, the associated risks are minimal. The risks of performing a FibroScan may be pain or discomfort during this process. In case of any of these complications, you will be provided care for the resolution of the problem, free of charge.

6. PROTECTION OF PERSONAL DATA AND CONFIDENTIALITY:

Personal information and information obtained from your medical evaluations will remain anonymous unless required by law, health authorities and institutional review boards. Relevant ethics committees may inspect your records to ensure that the study was conducted properly. The results of this research study may be presented at meetings or in publications. However, you will not be personally identified in any presentations or publications. In accordance with local regulations, you have the right to request access, correction or deletion of your personal information in writing to the study physician, including the justification for this. This request will be processed in accordance with local regulations.

7. COST AND OTHER CLARIFICATIONS:

Your participation in this study is voluntary and you may decide not to participate at any time, this decision will not affect the level of care you receive now or in the future. If you agree to participate, you will be asked if you are willing to be contacted for study follow-up. Your participation in this study will not affect the medical care you require.

It is important to note that the medical-nutritional evaluation, as well as the blood tests, abdominal ultrasound and Fibroscan will not generate costs.

By signing this informed consent, you or your legal representative are authorizing the uses and disclosures of your health information identified in this form. If you have questions about this project, you may ask questions at any time during your participation in this project.

TITLE OF THE PROTOCOL:

" Impact of diet on fatty liver "

This part must be completed by the Investigator (or his/her representative):

I have explained to Mr. _____ the nature and purposes of the research; I have explained to him/her about the risks and benefits involved in his/her participation. I have answered questions to the extent possible and have asked if he/she has any doubts. I agree that I have read and know the relevant regulations for conducting research with human subjects and I adhere to them. Once the question and answer session was concluded, the present document was signed.

_____ _____

Researcher's signature **Date**

VOLUNTEER'S STATEMENT

Name of patient or legal representative: _____ of _____ years of age. Sex: Female_____ Male_____ With the following address; Street_____ Number_____ Interior_____
Colony_____ City_____
State_____ Zip Code_____ Telephone_____

I acknowledge that I have been given the opportunity to ask questions regarding this research study and these questions have been answered to my satisfaction. By providing my consent, I acknowledge that my participation in this research project is voluntary and that I may refuse or withdraw from participation at any time I so desire without penalty or loss of benefits to which I am otherwise entitled.

My signature below means that I have read this consent form, understand its contents, and all my questions regarding this study have been answered by the study investigator or his/her staff.

PATIENT SIGNATURE	PHYSICIAN'S SIGNATURE
Patient's name	Name of Physician

SIGNATURE OF WITNESS 1	SIGNATURE OF WITNESS 2
Name	Name

In Veracruz, Veracruz. Mexico, to _____ of _____ of the year 2021

LETTER OF REVOCATION OF CONSENT

Protocol title: ***"Impact of diet on fatty liver disease".***

Principal investigator: Dr. Ana Delfina Cano **Contreras**

Place where the study will be carried out: Instituto de Investigaciones Médico-Biológicas de la Universidad Veracruzana.

Name of participant or legal representative: _____

I hereby wish to inform you of my decision to withdraw from this research protocol for the following reasons:

(This section is optional and can be left blank if the patient so wishes)

_____

_____

_____. If the patient so wishes, he/she may request that all the information collected about him/her as a result of his/her participation in this study be given to him/her.

_____	_____
Patient's signature	Date
_____	_____
Signature of Witness 1	Date
_____	_____
Signature of Witness 2	Date

c.c.p The patient. **(To be prepared in duplicate, one copy to be kept by the patient.)**