INFORMED CONSENT FORM

Project Title:-Studying Novel Scrum Markers For Hepatic Fibrosis In Patients With Chronic Hepatitis C Viral Genotype (4)

Principal Investigator: *Prof* .Mahmud.A.KHATTAB

CO-Principal Investigator: Prof .MOHMAMMAD.A.Sakr

Purpose/Description:

You are invited to participate in a research study that aims to find a non-invasive test to determine the degree of liver fibrosis as well as the grade of inflammation in the liver of patients infected with hepatitis C virus, genotype 4.you have been selected to participate in this study because you are chronicallyinfected with this virus, and you are being assessed for a possible anti-viral therapy that is available at the time being that is peg-interferon as well asRibaverin. So ,added to full clinical assessment, You are in need to be investigated by multiple serologic labaratoy tests and liver biopsy to determine the pattern of liver affection to see if you will be candidate for anti- viral standard of case therapy as not.A validated non-invasive serological test will enable patients like you to be assessed efficiently without the need of invasive procedure like liver biopsy. To achieve these aims we appreciate your participation in this project however your participation is entirely voluntary. Your decisions whether or not to participate will not affect your eligibility for optimum medical care and follow up if you decide to participate,

You are free to with draw your consent and to discontinue participation at any without prejudice to you.

Procedures:

You will be extensively assessed and monitored during your pre-treatment assessment protocol which include clinical evaluation, measuring body weight and height and waist and hip measurements. Also, blood tests required for

pre-treatmentprotocol judements will be conducted to you. Abdominal ultra sound and determining viral load and genotype will be done for you. What the research will get from you is that that among your routine serological amassment, a 5 ml blood in a tube will be stored to investigate serological parameters of the test in search.

Also,as a part of your routine pre-treatment assessment liver biopsy will be done to you U.S guided and by expert physicians

Risks:

Drawing blood by aneedly can sometime cause discomfort and bruising and rarely infaction.Liver biopsy will be followed by mild to moderate pain which will be controlled with analgesic, bleeding

can occur due to the procedure, however; it is rare and being in a hospital, You will be treated promptly, if it happened. Antibiotic chemoprophylaxis is usually given to you to prevent infection.

Benefit:

You personally will get benefit from this study as all these
Pre-treatment assessment will offered to you freely. Other patients like you infaceted with H C V-G4 will get benefit in the future if this test proved to be valid, in avoiding liver biopsy as an invasive test.

Confidentiality:

Information collected about you will be treated in a *strictly confidential manner and you will not personally be identified in the reporting of the result. Confidentiality of your data will be ensuredthrough coding of samples with numeric codes without your names. You will be assigned a unique study number. This unique study number will be linked to your identifier information in a database and on the hard copy of the Identifier Sheet on each questionnaire.*
This information will be secured by the Principal Investigator
(Prof .Mahmud Khattab) and locked in his office , separate from the laboratory and from other personnel. The database will require at least two levels of security (i.e., passwords), which will allow only authorized individuals to access the information. The Identifier Sheet from the questionnaire will be physically separated from the questionnaire, and stored in a locked cabinet. The questionnaires will retain only your unique study number. Biological samples will be labeled with the unique study number and no other identifier information.
NO identifier information that can be linked to study results or other data will leave the premises. All your data will be secured in the data management office that is secured and locked for access by the authorized persons supervising the clinical management.

***Costs / compensation*:**

There are no costs for participating in this study, all tests and procedures will be provided for free.

Right to withdraw:

Your participation is entirely voluntary, and you may withdraw your consent to participate at any time without a penalty. If you decide to withdraw from the study you can request that we destroy your stored samples and do not use the questionnaires in our analyses. If you decide to terminate your participation in this study, you should notify **Dr. Mahmud khattab Principal investigatory** ,by phone (0106040652)any time during working hours.

Principle Investigator: Dr Mahmoud Khattab

Signature

M. Khattab

I have read and understand the information on this form
I have had the information on this form explained

Subject's Signature Data

Signature Data