# CONSENT FORM

**STUDY TITLE:** PIVKA-II is an independent predictor of HCC presence and a better diagnostic biomarker than AFP in neoplastic lesions in cirrhotic livers.

**INVESTIGATOR:** Dr MUHAMMAD ALI QADEER, DR ZAIGHAM ABBAS, DR BUSHRA SHAHID, , DR ABEER ALTAF, DR MEHREEN SAYAL

**ORGANIZATION**: Dr. Ziauddin University Hospital Clifton

**LOCATION:** Outpatient Department

**INFORMATIONS FOR PATIENTS (PARTICIPANTS OF THIS STUDY)**

1. **PURPOSE OF THIS RESEARCH STUDY**

   You are being asked to participate in a research study designed to determine the diagnostic value of PIVKA-II and AFP in the diagnosis of HCC and further analyze the level of AFP and PIVKA-II in HCC patients.

2. **PROCEDURES**

   During your routine follow up, blood sample will be taken by laboratory from PIVKA-II assay was performed using enzyme-linked immunoassay principles. Test will be performed at the laboratory of Dr. Ziauddin hospital.

3. **POSSIBLE RISKS OR DISCOMFORT**

   Over all there are no risks or discomforts from the study. Slight discomfort from blood sampling may include bleeding, bruising, rash or soreness at sampling site.

   Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

4. **POSSIBLE BENEFITS**

   This study will help us in determining the value of PIVKA for detecting HCC. It will also help us to determine the screening role of PIVKA in comparison to AFP.
   This study will also help us to analyze the level of PIVKA and its clinicopathological relation with HCC.

5. **FINANCIAL CONSIDERATIONS**

   PIVKA test will be carried out which is part of the basic workup for disease and is commercially available. No extra investigations will be carried out apart from your routine ones, so no cost issues will be involved.

6. **CONFIDENTIALITY**

Your identity in this study will be treated as confidentiality. The result of this study may be published for scientific purposes, but will not give your name include any identifiable reference to you.
However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, or by ZMU ERC members.

**7. TERMINATION OF RESEARCH STURY**

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation.
In addition, your participation in the study may be terminated by the investigator with your consent.

**8. AVAILABLE RESOURCES OF INFORMATION**

Any further questions you have about this study will be answered by the principal investigator.
Name: Dr Muhammad Ali Qadeer
Phone Number: +923337123104

Any questions you may have about your rights as a research subject will be answered by
Name: Dr Muhammad Ali Qadeer
Phone Number: +923337123104
Email: draliqadeer@gmail.com

In case of a research related emergency, call
Day Emergency Number: 02135862937
Night Emergency Number: 02135862937

**9. Authorization**

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):

Date:

Participant Signature:

Date:

Principal Investigator Signature:

Date:

Signature of Person Obtaining Consent:

Date: