Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan

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Informed Consent Form (Screening)

Project Information	
Project Title: **Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan**	Version & Date: Ver 1, 30th Sept 2024
ERC ref no.: 2023-9084-26739	**Sponsor:** National Institute for Health and Care Research, UK
Principal Investigator: Dr. Zainab Samad Chair, Department of Medicine The Aga Khan University, Pakistan	Organization: Aga Khan University
Location: Karachi	Phone: 02134864660
Other Investigators: Dr Romaina Iqbal, Dr Imran Naeem, Dr Shiraz Hashmi, Dr Sajid Soofi, Dr Aysha Almas, Dr Saira Bukhari, Dr Saad Zafar, Dr Sawera Hanif	Organization: Aga Khan University
Location: Karachi	Phone: 02134864887

I am Dr/Mr/Ms _____ from the Department of Medicine, Aga Khan University, our team is doing research on "**Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan**." The principal investigator of this study is Dr. Zainab Samad, Chairperson, Department of Medicine, Aga Khan University, Pakistan.

PURPOSE OF THIS RESEARCH STUDY

Hypertension is a major public health concern globally. It is a significant risk for cardiovascular disease (CVD) and premature deaths. In Pakistan, the prevalence of other non-communicable diseases including diabetes mellitus, kidney disease, COPDs and cancer are on the rise. We

will ask a few screening questions from all individuals aged 35 and above regarding these diseases. This will help us in estimation of burden of chronic disease in the community that can help in developing preventive strategies to mitigate the associated risk.

PROCEDURES

As part of this study, you will undergo a brief screening survey of 10-15 minutes. In this regard we will ask you a brief screening questions about risk factors and diseases including hypertension, cardiovascular disease, diabetes and kidney disease and your weight height and waist circumference will also be measured to assess your obesity status. In addition, blood pressure will be measured thrice one-minute apart, if your BP is elevated in the first visit you will be followed up for the next visit within 2 weeks to confirm your hypertension status. In the next step all diagnosed hypertensive individuals will be approached for a detailed assessment. These individuals could be approached for future studies and followed up on the outcomes even after the completion of this study.

POSSIBLE RISKS OR DISCOMFORT

There are no risks involved as a result of your participation in this study except for your time.

POSSIBLE BENEFITS

There are no direct benefits for your participation, however, screening for illnesses will help identify the number of people suffering from diseases specified above & will benefit society overall.

FINANCIAL CONSIDERATIONS

There is no financial compensation for your participation in this research.

CONFIDENTIALITY

Your identity in this study will be treated as confidential. The results of the study may be published for scientific purposes but will not give your name or include any identifiable references to you. The data will be anonymized by assigning codes and personal identifiers will be removed. However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor or by AKU ERC members.

RIGHT TO REFUSE OR WITHDRAW

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.

AVAILABLE SOURCES OF INFORMATION

Any further questions you have about this study or if you have any questions you may have about your rights as a research subject will be answered by:

Name: Dr Imran Naeem on Phone Number: 021 3486 4887.

AUTHORIZATION

I have read and understood the consent form and volunteer to be part of this research study. I am aware that I will receive a copy of the informed consent form and I am aware of my right to discontinue my participation in the research study at any given time. I understand that this research will not violate any ethical human rights.

Name of participant (Printed or Typed):_____

Signature of participant:_____ Date:_____

Name and Signature of person obtaining consent: _____

Date:_____

Signature of Principal Investigator: _____Date: _____

For Participants unable to read

Witness:

I have witnessed the accurate reading of the consent form to the potential participants, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness Name: _____ Participant's Thumb Print: _____

Signature: _____Date:_____