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

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Informed Consent (workshop participation Phase 1)

Project Information	
Project Title: **Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan**	Version & Date:
ERC Project No:	Sponsor: NIHR
Principal Investigator: Dr Zainab Samad	Organization: Aga Khan University
Location: Karachi	Phone: 02134864660
Other Investigators: Dr Imran Naeem, Dr Sajid Soofi, Dr Romaina Iqbal, Dr Aysha Almas, Dr Saira Bukhari, Dr Zainab Siddiq, Dr Asim Shaikh, 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 and doing a research on "Evaluating the Effectiveness of a Multi-Component Intervention in improving hypertension, cardiovascular events, and deaths in adult rural population of Pakistan: A RE-AIM framework approach."

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 hypertension, including those on medication, has been found to be approximately 37%. However, there are high rates of undertreatment and underdiagnosis of hypertension in Pakistan. Addressing the prevention and control of CVD requires a multi-faceted approach that targets diverse populations across different settings. In some populations we have interventions that have been proven to be effective but have not been implemented for example in rural communities the COBRA-BPS trial has shown the effectiveness of a multi-component intervention in reducing blood pressure. However, the findings of this work have not translated to change in practice on the ground suggesting the need for implementation research to examine the best ways to implement this intervention in the real world. Hence, we aim to assess the impact of this evidence-based intervention when implemented at scale in rural communities. In this regard, we aim to conduct a series of workshops to get your inputs regarding identify and implement strategies to address burden of hypertension in rural communities and conduct focus group discussions to learn regarding your experience of implementation of COBRA intervention and the challenges encountered.

1. PURPOSE OF THIS RESEARCH STUDY

You are being asked to participate in a research study designed to improve blood pressure control. Intervention for this comprises of:

- Home Health education sessions
- Blood pressure measurements and referral to qualified medical practitioners for managing blood pressure as per need.

2. PROCEDURES

As part of this study:

- You'll be asked to participate in a series workshops, to identify implementation strategies for community-based intervention for addressing high blood pressure in rural population.
- You'll be requested to give your time (1 – 1.5 hour) for participation in focus group discussions to get your input regarding your experiences and challenges in implementing the community-based COBRA intervention.

3. POSSIBLE RISKS OR DISCOMFORT

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

4. POSSIBLE BENEFITS

- You'll be sharing your experience of intervention implementation, results of which will have the potential to improve the healthcare related to hypertension diagnosis management. This could potentially benefit both healthcare providers in the form of improved public perception, & patients in the form of improved blood pressure control.

5. FINANCIAL CONSIDERATIONS

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

8. 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.

9. 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 this study that may relate to or influence your willingness to continue participation.

Please notify Dr Imran Naeem, on 02134864887, of your decision so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent in case the sponsor of the study decides to terminate the study without prior notice due to reasons such as loss of funding.

10. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Principal Investigator:

  Name: Dr Zainab Samad

  Phone Number: 02134864660

- Any questions you may have about your rights as a research subject will be answered by:

  Name: Dr Imran Naeem

  Phone Number: 02134864887

11. 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.

Name of participant (Printed or Typed):

Date:

Signature of participant:

Date:

Signature of Principal Investigator:

Date:

Name and Signature of person obtaining consent:

Date: