

## **Participant information sheet**

**Title:** Exploring awareness, views and experiences of core outcome set development and use amongst stakeholders from low- and middle- income countries

### **Investigators**

- Lead Researcher (Jamlick Karumbi, University of Liverpool)
- Principal Supervisor (Professor Paula Williamson, University of Liverpool, UK)
- Co-Supervisors (KEMRI: Dr. David Gathara; University of Liverpool: Professor Bridget Young, Dr. Liz Gargon, Dr. Sarah Gorst)

We invite you to take part in our research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask if you would like more information or if there is anything that you do not understand. Thank you for reading this.

### **Key information for you to consider**

#### **What is the purpose of the study?**

Over recent years there has been an increase in the development and use of core outcome sets (COS) in clinical trials and routine care. A COS is an agreed standardised set of outcomes, which represent the minimum set of outcomes that should be measured and reported in a specific condition.

Many of the COS that have been developed and currently in use are led by researchers from high income countries. Few COS projects have been led by or involved stakeholders from low- and middle-income countries (LMICs). This study will explore awareness, views and experiences of core outcome set development and use amongst stakeholders from low- and middle- income countries. We hope the findings will help us design approaches to improve the development and use of COS in LMICs.

#### **Why have I been chosen to take part?**

You have been chosen to take part based on contribution to research and clinical work in LMICs and your membership in The Global Health Network (TGHN).

#### **What will happen if I take part?**

You will receive a link from TGHN inviting you to participate in an online survey. The survey comprises a few questions about your knowledge and experiences with COS, and should take about 20 minutes of your time.

#### **How will my data be used?**

The University of Liverpool processes personal data as part of its research and teaching activities in accordance with the lawful basis of ‘public task’, and in accordance with the University’s purpose of “advancing education, learning and research for the public benefit”.

Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University's research.

The supervisor acts as the Data Processor for this study, and any queries relating to the handling of your personal data can be sent to:

**Prof Paula Williamson,**  
Department of Health Data Science, Institute of Population Health,  
Block F/Waterhouse Building,  
University of Liverpool,  
Liverpool,  
L69 3BX:  
Email address: [P.R.Williamson@liverpool.ac.uk](mailto:P.R.Williamson@liverpool.ac.uk)

### **Expenses and / or payments**

There are no envisaged extra expenses for this research. As such, there will be no reimbursements or payments for participating in this research.

### **Are there any risks in taking part?**

There are no known or anticipated risks to the participants of this research, the material being discussed, and the data being collected is not of a sensitive nature.

### **Are there any benefits in taking part?**

You will be helping develop our understanding of how to improve the development and use of COS in LMICs in research and clinical practice.

### **What will happen to the results of the study?**

After the study has finished, the results will be written up as part of Jamlick Karumbi's postgraduate research thesis and submitted for examination to the University of Liverpool. The results will also be submitted for publication in an academic journal and presented at conferences. All the responses will be anonymized.

### **What will happen if I want to stop taking part?**

If you decide to take part but then change your mind, you are free to do so at any time without giving a reason. Please note you cannot request withdrawal of your data after anonymization.

### **What if I am unhappy or if there is a problem?**

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Prof Paula Williamson, [p.r.williamson@liverpool.ac.uk](mailto:p.r.williamson@liverpool.ac.uk) and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Ethics and Integrity Office at [ethics@liv.ac.uk](mailto:ethics@liv.ac.uk). When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.