

## **RESEARCH PARTICIPANT INFORMED CONSENT FORM- SCHOOL PRINCIPAL**

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**Research project:** Development and testing of digital learning resources for informed health choices and participation in informed dialogues about health in Kenya (CHOICE PROJECT)

### **1. INTRODUCTION**

CHOICE project is a research collaboration that seeks to improve health literacy by developing and testing of resources that can be used to enable young people to make informed personal choices about their health (health choices learning-resources) and to participate as scientifically literate citizens in informed debate about health policies (health policy learning-resources)

In Kenya, the study is being conducted by researchers from the Tropical Institute of Community Health and Development (TICH) and will involve continuous interaction with students, teachers, development partners and policymakers, and researchers.

Your school has been selected to participate in the process evaluation study for a period of one school term (first term 2022), with a follow-up after one year to evaluate the delivery of the learning resource. We will select about 8-10 students to participate in interviews and focus group discussions. We note that these students cannot alone decide by themselves since they have not yet reached the legal age of consent for Kenya. We are therefore seeking permission for your students to participate in this study. The information in this document is meant to help you decide whether or not your students should take part in this study but first they're a few things to note.

- In addition to your acceptance, you will require to inform the students and the school management board about participation in this study.
- We anticipate that once you agree to participate your school will be in the study for a period of one school term (first term 2022), with follow-up after one year.
- You will be offered a copy of this form for your future reference.
- Please feel free to ask if you have any questions or concerns at any time before the start or during the conduct of the research.

The aim of this collaborative research project is to improve population health outcomes by improving health literacy in low-income countries. We will do this by developing and evaluating two strategies for improving health literacy: learning resources that can be used to enable young people to make informed personal choices about their health (health choices learning-resources) and to participate as scientifically literate citizens in informed debate about health policies (health policy learning-resources)

### **2. HOW WILL THE STUDY BE CONDUCTED?**

The study will be conducted in over 80 schools in Kenya, during school term. Some schools will be allocated to the intervention arm and others to the control arm. All the selected schools will be allocated to either the intervention arm or to the control arm using computer-generated randomization. Schools in the

intervention arm together with their teachers will learn resources developed. In the control arm, students will continue with the curriculum as normal during the school term. The claim evaluation tool will be given to each student to assess whether he/she was able to apply knowledge gained from the learning resources. All the students in both arms of the trial will complete the questionnaires in their classrooms at the end of the term. This questionnaire will require approximately one hour. We will administer the questionnaires again after one year to find out if the children retained what they learned. All the schools that were allocated to the control arm will also get the learning resources after the trial has been concluded and the CLAIM questionnaires have been collected. In addition to the data from the CLAIM evaluation tools, we will ask your school to provide us with data on student's class performance on the ministry of education curriculum (end of terms scores) as well as their attendance data for the period of the trial. We will interview some teachers, education officers and students from schools in the intervention arm regarding the process of using resources.

### **3. POSSIBLE RISKS TO YOUR CHILD**

We anticipate that your students' participation in the study/research presents no risk to them. Your students' participation in the study will not affect their performance at school.

### **4. POSSIBLE BENEFITS TO YOUR CHILD**

There will be no direct benefit to your students from participating in this study and there is no promise of gaining any material or financial benefit from the project currently or in the future.

Your students' participation in the study could contribute to gaining new knowledge that will be used to design resources aimed at improving health literacy in low-income countries. Your students may be equipped with skills to enable them obtain, process and understand health information that they might need to make appropriate healthcare decisions. Your students will benefit from free health information.

### **5. COST TO THE PARTICIPANT**

You will incur no cost whatsoever as a result of your students taking part in the study.

### **6. COMPENSATION**

Your students or you will not gain any form of compensation, monetary or otherwise.

### **7. CONFIDENTIALITY**

The information your students may give during the conduct of this research will be kept confidential in accordance to the ethical standards agreed upon by the local and international organizations governing the conduct of research involving human participants. Any information resulting from this study, if published in scientific journals or presented at scientific meetings, will not reveal your students' identity.

### **8. RIGHT TO REFUSE/ WITHDRAW YOUR CHILD'S PARTICIPATION**

Your students' participation in this research is purely voluntary and you are free to decline to take part or withdraw your students' participation at any time without any repercussions.

**9. QUESTIONS ABOUT THE RESEARCH**

In case of any further questions, please contact Prof. Margaret Kaseje, the Principal Investigator in Kenya working at Tropical Institute of Community Health and Development (TICH): Tel: 0715021955 or Ms. Faith Chesire on 0721576525.

**10. DECLARATION OF CONSENT**

The information about this study has been availed and explained to me and all my questions have been answered. I have read this form and I feel that I have had enough information and time to consider my decision to allow my students participate in the study. I fully understand that by signing this form, I do not waive any of my legal rights, nor does it relieve the study investigators their duty (liability), but merely indicates that I have been informed about the research study in which I am voluntarily agreeing my students to take part. A copy of this form will be availed to me. Having understood all the information pertaining to this study I therefore agree to my students' participation in this study by appending my signature and name below.

**Research Participant's Parent/Guardian**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

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Date: \_\_\_\_\_

Tel: \_\_\_\_\_