CHOICE PROJECT
Safety Monitoring and Adverse Events Form.

AE= Adverse events. SAE= Serious Adverse Events.
This will be used to collect and report adverse events that occur on site during the research project. The Principal Investigator (PI) should be notified regarding any AE or SAE (within 24 hours).

I) **STUDY TITLE**: Effects of Informed Health Choices secondary school resources on the ability of Kenyan students to think critically about health

II) **STUDY OVERVIEW:** This is a two-arm cluster randomised trial evaluating the effect of the informed health choices digital learning resources on the ability of lower secondary school students to think critically about health. The study will be taking place in over 80 schools during the first term of the academic year 2020-2022. Students in form one from selected schools that fall in the intervention arm will learn the lessons over a period of five to twelve weeks. The same students in the control arm will continue with the current curriculum as usual. At the end of the term, all the students in both arms (control and intervention) of the trial will complete a questionnaire with multiple-choice questions that assess an individual's ability to apply concepts covered in the resources.

III) **CONFIDENTIALITY:** All materials collected are for research purposes only and data will be kept in strict confidence.

IV) **ADVERSE EVENT INFORMATION**: Any untoward or unfavorable occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research is considered an adverse event.

A Serious Adverse Event (SAE) could result in

- Death
- Prolonged hospitalization
- Causes persistent or significant disability etc.

We anticipate that participation in this research study presents no risk to the individual that may result in a serious adverse event.

V) EXPECTED RISKS: None in relation to participating individuals' health.

VI) UNANTICIPATED PROBLEMS: Unanticipated problems, usually not directly related to the study may affect the delivery of the intervention. Any arising events that may affect delivery of the intervention should be reported to the Principal Investigator in 48 hours.

AE, SAE and UP EVENT REPORTING FORM

Event ID	**Date of Event**	**Describe the event**	**Relationship to the research**	**Site of the Event.** (*Provide school name and indicate the District*)	**Has the event been reported to the P.I?** *Please tick (√) if yes*	**Action taken/recommended.** **(***If any, please give details below)*
001			☐ Related ☐ Probably related. ☐ Possibly related. ☐ Unrelated. ☐ Unknown			

002			☐ Related ☐ Probably related. ☐ Possibly related. ☐ Unrelated. ☐ Unknown			

Principal Investigator's Contact details.

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