APPENDIX I.

INFORMED CONSENT FORM FOR PARTICIPATORY RESEARCH ACTIVITIES

Informing the design of interventions to reduce reliance on antibiotics while minimizing unintended consequences

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Protocol Title: Antimicrobials in Society (AMIS) Project Uganda: Understanding the role of antimicrobials in daily life in Tororo, Wakiso and Kampala districts of Uganda through three entry points: Health Care, Farming and Urban Work.

Site of Research: Tororo, Wakiso and Kampala, Uganda

Principal Investigator: Ms Susan Nayiga (IDRC) and Dr. Clare Chandler(LSHTM)

Investigators and Institutions: Ms Nabirye Christine (IDRC), Ms Miriam Kayendeke (IDRC), Dr Laurie Denyer Willis (LSHTM), Prof. Sarah Staedke (LSHTM/IDRC)

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Introduction

Susan Nayiga and colleagues from the Infectious Diseases Research Collaboration (IDRC) and the London School of Hygiene & Tropical Medicine (LSHTM) are carrying out a research study to understand how medicines used to treat different types of infections have become a part of health care and daily life in Uganda. This study will be conducted in three places: 1) public and private sources of health care and surrounding communities in Nagongera sub-county, Tororo district; 2) farms of different scales and technologies of production in Wakiso district and; 3) Soweto and Banda informal settlements in Kampala district.

How will this study be done?

We are inviting key stakeholders and study participants including public and private healthcare providers and residents of surrounding communities, farmers, day wage urban workers, local leaders, farmers' associations and informal groups to take part in feedback meetings every three months. In each site we anticipate engagements with 15-20 individuals at each three-monthly time point.

What will happen if I take part in this study?

If you agree, you will take part in feedback meetings every three months. We are interested to observe and hear opinions. There are no right or wrong answers. We simply want to hear your opinions about on-going research and speak to you about findings and analysis. We shall also observe your actions arising out of research feedback. We will take notes during the feedback meetings and may ask you some questions. Afterwards, we will type up our notes into a computer for analysis.

How will the information collected in this study be used?

The information we collect will be used by project investigators and may be shared with other researchers to answer questions about how medicines are important to people in different settings. The findings will be

important to provide locally relevant advice for governmental and non-governmental programmes that want to ensure that medicines continue to work effectively for everyone.

We are conducting this study in collaboration with colleagues from Mahidol University and the Ministry of Public Health in Thailand and colleagues from LSHTM. Information collected in this study will be shared with our research partners so that we can compare findings from Uganda and Thailand. The information collected may also be shared with other researchers outside of the study (not part of the AMIS group) who request permission to access the data. However, no personal information about you will be included in the information shared. Data collected in the study will be stored for a minimum of 10 years and a maximum of 15 years following project completion on the main IDRC server in Kampala and the LSHTM server in London.

Where will the study take place?

The feedback meetings will take place at a convenient location in Tororo, Wakiso, and Kampala districts.

How long will the study last?

Overall, the study will last for about 15 months in your area and during this period up to 6 feedback meetings will be held. Each feedback meeting will last half a day.

Can I stop taking part in the participatory research activities?

Participation in one feedback meeting does not mean you must participate in all meetings. You can decide to stop participating at any time and for any reason. Just tell the project researcher right away if you wish to stop.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study, or to stop taking part at any point. If you decide not to take part in this study, you can tell one of the study team your wishes and there will be no penalty to you.

What risks can I expect from being in the study?

Participation in any research study may involve a loss of privacy or confidentiality. Information you provide will be recorded, but your name will not be used in any reports. No one else will have access to the recordings of your voice and this will be destroyed after transcription is complete. We will remove any personal information to ensure that you are not identifiable in any interview records or reports of the information provided. The information obtained from these study activities will be locked up at our project offices. All personal information will be stored electronically in a secure, password protected database to ensure privacy.

Will I be paid for taking part in this study?

You will not be paid for taking part in this research, but you will be given 20,000 Uganda shillings to refund the cost of your transport.

Are there benefits to taking part in the study?

We will not provide any direct benefit to you for participating in this study. The information that you provide will help researchers gather feedback on research findings and cross-check that we have adequately captured experiences of study participants within our analysis. The meetings will be used as a platform for generating local ideas for interventions on AMR and antibiotic use. The participatory research activities will provide an opportunity for our research findings to have immediate impact through action by local leaders, healthcare workers and farmers.

Who can answer my questions about the study?

If you have any questions, comments or concerns, or feel that you have been harmed from taking part in these activities, please talk to the researchers first. Contact Ms Susan Nayiga, the principal Investigator of the AMIS Uganda Project on +256 (0) 752900565 or the Infectious Diseases Research Collaboration on telephone number +256 (0) 414 540 624.If for any reason you do not wish to do this, or you have questions or concerns about your rights, you may contact Dr Erisa Mwaka, the Chair of the School of Biomedical Sciences Research and Ethics Committee (SBS REC) at telephone number +256 (0) 752 575050.

WHAT YOUR SIGNATURE MEANS

Your signature below means that you understand the information given to you in this consent form about your participation in the study and agree with the following statements:

1 "I have read the consent form concerning this study (or have understood the verbal explanation of the consent form) and I understand what will be required of me and what will happen to me if I take part in it."

2 "My questions concerning this study have been answered by the person who signed below."

3 "I understand that at any time, I may withdraw from this study without giving a reason."

4 "I agree to take part in this study."

If you wish to participate in this study, you should sign on the following page. If you do not agree to quotes or other results arising from your participation in the study being included, even anonymously, in any reports about the study, please tell the researcher now.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Name of Participant (printed)

Signature of Participant Date/Time

Name of Researcher administering consent (printed)

Signature of Researcher Date/Time

If the participant is unable to read and/or write, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to participate in the study, the witness should print the name of the participant above, and then the participant should provide their fingerprint. Then the witness should print their name, provide their signature, and date the consent form below. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant, and that informed consent was freely given by the participant.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date/Time

MAKERERE UNIVERSITY
SCHOOL OF BIOMEDICAL SCIENCES
APPROVED
VALID UNTIL
25 APR 2019
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