APPENDIX B.

INFORMED CONSENT FORM FOR INDEPTH INTERVIEWS (KEY STAKEHOLDERS)

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 who are knowledgeable about antimicrobial resistance in Uganda to take part in in-depth interviews. Stakeholders may include policy-makers, health care workers, regulators, consumer groups, representatives from non-governmental organisations (NGOs), civil societies, researchers and/or selected community members. The aim of the interviews is to reach a better understanding of antimicrobial resistance (AMR) policies and initiatives, and ongoing research related to AMR. We plan to carry out about 20-40 in-depth interviews with stakeholders throughout the study period. This information will help us understand the findings from the ethnographic field work in the community better and answer any questions arising from the fieldwork.

What will happen if I take part in this study?

Today, we would like to ask you questions about the use of medicines in everyday life, and why people rely on these medicines. We will also ask questions about policies and guidelines related to use of medicines in Uganda. We will take notes of the discussion and will record the interview using a digital voice recorder. Afterwards, we will transcribe the audio recordings 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 best to design interventions to reduce reliance on medicines, while avoiding unintended bad outcomes. 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 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 fieldwork for this study will take place in Tororo, Wakiso, and Kampala districts. We will focus on health facilities, places where people seek care or where medicines are sold, households, farms, and surrounding neighborhoods. The in-depth interviews will take place in settings convenient to stakeholders, most likely in and around Kampala but also elsewhere and even by telephone or Skype.

How long will the study last?

Overall, the study will last for about 15 months. Today, the interview will last about 30-90 minutes.

Can I stop taking part in the in-depth interview?

You can decide to stop participating at any time. 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 the in-depth interview?

You are free to choose not to participate in the in-depth interview, or to stop taking part at any point. If you decide not to take part in the interview, 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.

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 and policy-makers to understand how people use antimicrobial medicines, the context of this medicine use and how efforts to address antimicrobial resistance may take on board the importance of these medicines for people's everyday lives and livelihoods.

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.

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