To: Corinne Carlan
From: Leigh Fern, Chair
COUHES
Date: 03/18/2015
Committee Action: Exemption Granted
Committee Action Date: 03/18/2015
COUHES Protocol #: 1503006974
Study Title: Private Sector Supply Chains for Malaria RDTs in Uganda

The above-referenced protocol is considered exempt after review by the Committee on the Use of Humans as Experimental Subjects pursuant to Federal regulations, 45 CFR Part 46.101(b)(2).

This part of the federal regulations requires that the information be recorded by investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. It is necessary that the information obtained not be such that if disclosed outside the research, it could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

If the research involves collaboration with another institution then the research cannot commence until COUHES receives written notification of approval from the collaborating institution's IRB.

Any changes to the protocol that impact human subjects, including changes in experimental design, equipment, personnel or funding, must be approved by COUHES before they can be initiated. You should retain a copy of this letter for your records.
Consent script

My name is ______. I am part of a project with Massachusetts Institute of Technology and we are working with Malaria Consortium in conducting research on scaling up rapid diagnostic for malaria in private sector clinics and drug ships in Uganda.

Your participation in this survey is entirely voluntary and you can choose to end your participation at any time without any negative consequences.

Your name will not be recorded, and any information you provide will be confidential. You can choose not answer any questions you wish.

Your views are important as we hope to understand how manufacturers, importers, distributors, retailers and the overall public health goods supply chains in Uganda make decisions about whether to stock, carry, and/or sell products.

At the end of the project, we hope to have a better understanding of these preferences and decision-making process, with which we can use to develop better relationships with the private sector and increase access to important health products.

Exemption Granted on 18-MAR-2015
Recruitment script

My name is ______. I am part of a project with Massachusetts Institute of Technology and Malaria Consortium conducting research on the introduction of rapid diagnostic devices for malaria into supply chains in Uganda.

My colleague ______ from [Malaria Consortium or other Project Partner] has suggested that you would be interested in sharing your experience with [producing, distributing, or selling] malaria rapid diagnostic tests. We would like to ask you a range of questions to better understand your decision in choosing to [produce, distribute, or sell] these products.

If you are interested in sharing your experiences, please allow me to explain the project to you more and to ask for your consent to participate in our study.

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