# PARTICIPANT INFORMATION SHEET AND CONSENT FORMS

**Study title: Integrating community-directed initiatives against neglected tropical diseases**

**Questions and contact information**

If you have any questions about this project you are free to contact any member of the research team. The name and contact details of the project leader are:

Dr. Safari M. Kinunghi,

National Institute for Medical Research (NIMR), Mwanza Centre,

P. O. Box 1462, Mwanza, Tanzania

Tel: 028-2500399; Mob: 0784 318096; email: kinunghi\_csm@hotmail.com

The ‘*Integrating community-directed initiatives against neglected tropical diseases’*research study (hereafter called the ‘Integrated Disease Control Study’) is investigating whether combining the delivery of disease control programs improves cost-effectiveness and uptake. The two disease control programs that are being combined are the i) mass worming program and ii) the mass dog rabies vaccination program. This study is being implemented in the Mwanza and Simiyu Regions.

**Why is this project important?**

We are conducting this study to improve our understanding of how to deliver disease control programs against neglected tropical diseases. The goal is to reduce the disease burden of worms and rabies in humans.

**Why is it important to treat the participants against worms?**

Worms are a major public health problem in Tanzania. Adults and children carry worms, however their impact primarily affects children, causing physical and mental impairment. We would therefore like to treat the participants and their children against worms.

**Why is it important to vaccinate the participants’ dogs against rabies?**

Domestic dogs are the main host of rabies. If domestic dogs are vaccinated against rabies the disease disappears in dogs, livestock, wildlife and humans. We would therefore like to vaccinate the participants’ dogs against rabies.

**What does participation in this project involve?**

You and / or your children will be given a worming treatment to be taken by mouth. If you have dogs we recommend that you allow us to vaccinate them with an inoculation in to the skin of the neck. Your participation will take no more than 15 minutes.

You may also be asked to take part in a voluntary interview (on your own) or a focus group discussion (involving several people). These discussions help us to better understand whether the community supports such intervention activities. In addition we may visit your house to ask if you would mind answering a few questions about how many people in your household were treated and how many dogs were vaccinated. These questions allow us to estimate how many people in the village were treated and how many dogs were vaccinated. Participation in all of these activities is entirely voluntary and non-participation will not prejudice you against voluntary participation in other activities.

**Are there any benefits or risks?**

The benefits are that you and your children will be free from worms and the impacts that they have on your health. In addition your dogs will be protected against rabies. If sufficient dogs are vaccinated, rabies will not be able to be maintained in the dogs in your community. This will make it much less likely that the people and livestock in your community will be affected by rabies.

There is a small possibility that you will feel sick after taking the worming treatment. If this happens please return to the clinic to be examined by the health worker.

**Confidentiality**

All information which you will give us (including your name/child’s name) will be treated as confidential. You or your child will be given a number, which nobody, except members of the research team, will be able to identify.

**Participation**

We hope that you and your children will participate in this research project. However, you are free to decide for them not to participate and that by not participating in this study they will still receive all health care benefits and any future benefits of disease control measures in your area. In the eventuality that you do not want your child to participate later you can withdraw from this research at any time.

**What you are required to do?**

After being given information about this study you are allowed to ask questions on anything which you do not understand. If you agree to participate in this research project, you will be required to sign a consent form.

**Approval**

This study has been approved by the National Institute of Medical Research, the Lake Zone Review Board (Tanzania) and the Washington State University Institutional Review Board (USA).

The participant will receive a copy of this consent form.

**Informed consent form for participants and, if required, legal guardians:**

1. I have read / been read the participant Information Sheet for the Integrated Disease Control Study which explains the purpose of the study and requests for my consent or the consent for my child to participate in the study.

2. All the questions I had about this project have been answered.

3. I have clearly understood what I have to do if I agree to take part or for my child to take part in this study.

4. I also know that I have the right to withdraw my child and /or myself from this study at anytime if I do not wish to continue.

5. I know that all the information I give will remain confidential.

6. I agree for my child and / or myself to take part in the study.

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| **Participant identification number** | **Participant name**  | **Signature or Thumbprint**  | **Date**  |
|  |  |  |  |
|  | **Guardian name (if required)** | **Signature or Thumbprint** | **Date** |
|  |  |  |  |

**Researcher signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Researcher name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# KIAMBATANISHO CHA I. TAARIFA KWA MSHIRIKI NA HATI YA RIDHAA

Utafiti huu unahusu ugonjwa wa kichocho cha kukojoa damu. Kwa jina jingine ugonjwa huu huitwa “birharzia”. Ugonjwa huu husababishwa na minyoo na husambazwa na vijidudu vinavyobebwa na konokono. Mradi huu unatekelezwa katika vijiji vya wilaya ya Misungwi.

**Utafiti huu una umuhimu gani?**

Utafiti huu umelenga katika kuelewa hali ya ugonjwa katika vijiji vya wilaya ya Misungwi kwa kupima viashiria vya ugonjwa katika mkojo. Lengo ni kutafuta njia za kupambana na maambukizi ya ugonjwa wa kichocho katika wilaya ya Misungwi na mkoa wa Mwanza kwa ujumla.

**Kwa nini ni muhimu kuchora ramani ya kaya ambako washiriki wanaishi?**

Tungependa kujua kama watoto wanaoishi kwenye kaya ambazo ziko karibu na maji yaliyotuama kama madimbwi, malambo majaruba n.k. ambayo yana konokono wana kiwango cha juu cha maambukizi ya minyoo ya kichocho ukilingnisha na watoto wengine kijijini.

**Je, ushiriki katika mradi huu unahusisha mambo gani?**

Mtoto wako atatakiwa kutoa sampuli ya mkojo ambao utapimwa kuona kama una mayai ya minyoo ya kichocho na viashiria vya kinga ya mwili dhidi ya ugojwa wa kichocho.

**Je, kuna faida au madhara yatokanayo na kushiriki katika utafiti huu?**

Ugonjwa wa kichocho una madhara kwa afya ya binadamu. Kama utamruhusu mtoto wako kushiriki katika utafiti huu, utakuwa umeisaidia serikali ya Tanzania katika kuweka mikakati ya kupambana na ugonjwa wa kichocho katika wilaya ya Misungwi na maeneo mengine ya Tanzania. Vilevile, kama mtoto wako atakutwa na maambukizi ya ugonjwa wa kichocho utapata matibabu bure.

**Utunzaji wa taarifa za utafiti**

Taarifa zote zitakazokusanywa (ikiwa ni pamoja na majina) zitatunzwa kwa usiri mkubwa. Washiriki watapewa namba ya utambulisho ambayo hakuna mtu yeyote atakayeweza kuitambua isipokuwa watafiti peke yao.

**Mtu wa kumwuliza kama una maswali:**

Kama una maswali yoyote kuhusiana na mradi huu wa utafiti, jisikie huru kumwuliza mtu yeyote katika timu ya watafiti. Jina la kiongozi wa mradi pamoja na anwani yake ni:

Dr. Safari M. Kinung’hi,

Taasisi ya Taifa ya Utafiti wa Magonjwa ya Binadamu, Kituo cha Mwanza,

S. L. B. 1462, Mwanza, Tanzania.

Simu ya mezani: 028-2500399; Simu ya mkononi: 0784 318096;

Barua pepe: kinunghi\_csm@hotmail.com

**Kushiriki**

Tunatumaini utamruhusu mtoto wako kushiriki katika utafiti huu. Hata hivyo una haki ya kutomruhusu mtoto wako kutoshiriki katika utafiti huu bila kupoteza haki yako na ya mtoto wako ya kupata huduma za afya. Vilevile una haki ya kumtoa mtoto wako katika ushiriki wa utafiti huu wakati wowote ukiamua kufanya hivyo.

**Je, ni kitu gani unatakiwa kufanya?**

Baada ya kupewa taarifa kuhusu utafiti huu, unaruhusiwa kuuliza swali kuhusu kitu chochote ambacho huelewi. Kama utakubali kumruhusu mtoto wako kushiriki katika utafiti huu, utatakiwa kutia sahihi hati ya ridhaa.

**Hati ya ridhaa ya mshiriki:**

1. Nimesoma/nimesomewa maelezo kuhusu mradi wa utafiti wa ugonjwa wa kichocho cha kukojoa damu. Maelezo niliyopata yanatoa taarifa kuhusu malengo ya mradi na jinsi ya kushiriki. Vilevile nimeombwa kutoa ridhaa kwa mtoto wangu kushiriki katika utafiti.

2. Maswali yote niliyokuwa nayo kuhusu mradi yamejibiwa kwa ufasaha.

3. Nimeelewa kile ninachotakiwa kufanya endapo nitaamua kumruhusu mtoto wangu kushiriki katika mradi huu wa utafiti.

4. Vilevile ninaelewa kuwa ninayo haki ya kumtoa mtoto wangu kutoka katika utafiti wakati wowote bila kupoteza haki yangu nay a mtoto wangu ya kupata huduma za afya.

5. Ninatambua kuwa taarifa zote zitakazotolewa katika utafiti huu zitatunzwa kwa usiri mkubwa.

6. Ninaamua kumruhusu mtoto wangu ashiriki katika mradi huu wa utafiti

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| **Namba ya utambulisho ya mshiriki** | **Jina la mshiriki**  | **Sahihi au alama ya dole gumba**  | **Tarehe**  |
|  |  |  |  |
|  | **Guardian name (if required)** | **Signature or Thumbprint** | **Date** |
|  |  |  |  |

**Researcher signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Researcher name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**