## Information Sheet /Informed Consent

## Information sheet

**Eliminating the major Helminth Neglected Tropical Diseases from the Lower Mekong Basin**

**The Magic Glasses E-joint Research Program**

**Participant Information Sheet**

**Researcher:**

I (name of researcher), representing the (local study partner in Cambodia, Thailand and Lao) and the Australian National University, would like to invite you to participate in our study. However, before you can make a decision, we would like you to read this information sheet, discuss it, ask question and then tell us if you want to participate in this activity.

**Project Title:** Eliminating the major Helminth Neglected Tropical Diseases from the Lower Mekong Basin – “The Magic Glasses E-joint Research Program”

**General Outline of the Project:**

**Description and Methodology:**

The (name of partner agency in Cambodia, Thailand and Laos) and the Australian National University are conducting a study to develop a health promotion/intervention package on intestinal worm infections and liver fluke. Intestinal worms are a common cause of illness among children and can lead to anaemia, malnourishment and impaired academic ability. Liver fluke infection on the other hand, is associated with liver (hepatobiliary) disease. The most serious consequence of liver fluke infection however, is its role in the aetiology of cholangiocarcinoma (CCA), a highly fatal bile duct cancer.

The main strategy to control for these infections is through mass drug administration using deworming tablets. However, deworming does not prevent reinfection and needs to be repeated regularly. With this health promotional/intervention package, we hope to reduce the incidence of intestinal worm infections and liver fluke among children and residents in the country. This health promotion package will be delivered in some villages but not in others. The study will be conducted among residents (aged 5 years and above) in 12 villages in one municipality in a province. We hope to target approximately 100 households per village (500 residents) and we will follow them up for the duration of one year.

This study is approved by (place holder) which looks after the rights of the research participants and ensure their safety.

We have randomly selected your household in this survey. Thus, we are inviting you and all the members of this household aged 5 years and above to participate, and the following procedures will be done:

|  |  |
| --- | --- |
| **Activities** | **Schedule of data collection** |
| * + 1. Household interview with the household head.
 | At start of the study only. |
| * + 1. Collect two stool samples (all household members aged ≥5 years)
 | These will be done upon joining the study and at study follow-up. |
| * + 1. Obtain a very small amount of blood through finger prick (all household members aged ≥5 years) to determine if you have anemia.

Anemia is a condition that develops when your blood lacks enough healthy red blood cells or hemoglobin. This can cause paleness, tiredness or fatigue, and weakness.  |
| * + 1. Height and weight measurements

(all household members aged ≥5 years) |
| * + 1. Nutritional assessment

(all household members aged ≥5 years) |
| * + 1. Answer a questionnaire about what you know or feel about intestinal worms and liver fluke and the things that you do to prevent these infections.

(all household members aged ≥5 years) |
| * + 1. Provision of medicine for intestinal worms (Albendazole) and liver fluke infections (Praziquantel)
 | This will be done at the start of the project. We will also provide medicine at the end of the project if you still have intestinal worm/Ov infections to help cure it.  |

**Use of Data and Feedback:** The information we obtain from you will help us determine how effective a health promotion/intervention package is in the control of intestinal worms and liver fluke infections among the residents. Feedback will be given to the officials of the Ministry of health and/or the Department of Education for possible integration of the health promotion package in the community and schools.

**Project Funding:** This research is funded by a grant from the Australian National Health and Medical Research Council.

**Participant Involvement:**

**Voluntary Participation & Withdrawal:** Your participation is voluntary. You can choose not to participate or to withdraw at any stage with no explanation required. You and your children can also choose not to answer any questions. Whatever you decide, your decision will not impact the normal health services you receive.

**Location and Duration:** If you consent, all the activities will be conducted in your household. This will take some 45 mins to 1 hour of your time.

**Risks:** We do not see any harm that will come to you from participating in this project. But you may experience discomfort and a slight pain with the finger prick, but these are temporary and will disappear after a while. We would like to ask you to provide consent for your children to be involved (aged 5-11). If your child/children are aged 12 or over we will also ask them individually if they would like to be involved.

The Ministry of Health will provide the medicine (Albendazole and Praziquantel) for you. These medications have been proven to be safe and effective; and they are being used throughout the world. These medications are known to have a very low risk reaction, but in case of any adverse reactions, the Health Authorities (who have many years of experience using these medications) will provide support and assistance.

**Benefits:** There will be no direct benefit to you and your child; we will also not provide any incentives to you or to them for your or their participation. However, the information we will obtain from you, your child and from all the other study participants will help us determine the impact of a health promotion/intervention package in the control of intestinal worms and liver fluke infections among the residents. This health promotion/intervention package will be delivered in communities and schools and can help the people to be aware about these infections and how to prevent themselves from getting sick.

**Confidentiality:**

**Confidentiality:** The researchers in this project guarantee confidentiality of the data as far as the law allows. We will not be collecting any personal information about you or your family. The information you provide will not be able to be connected with you. Only the study researchers will have access to the data you provide and any reports which will be written using this project’s data will not contain any information that identifies any child or family as participants in this study.

**Privacy Notice:**

Australian privacy rules require me to tell you how my University handles your private information, and you can ask me to give you more details of that or how you can find out what information we have about you and to fix it if it is wrong.

**Data Storage:**

**Where:** The data collected from you will be stored in an encrypted server at the Australian National University. Access will only be by the lead investigator. As described above, there will be no personal information collected.

**How long:** The data you provide will be stored for 5 years from the date of the data collection. Following that period, the de-identified data will be archived.

**Queries and Concerns:**

**Contact Details for More Information:** If there is anything you do not understand or if you want more detail of the study please contact the lead investigator, Dr. Darren Gray at Darren.gray@anu.edu.au OR

The local study team representative

**CAMBODIA**

**Dr Virak Khieu (**Virak.khieu@gmail.com)

Ministry of Health – Cambodia

**THAILAND**

**Prof Banchob Sripa** (banchob@kku.ac.th)

Faculty of Medicine, Khon Kaen University

**LAOS**

**Dr Somphou Sayasone,**

Ministry of Health, Laos

**Ethics Committee Clearance:**

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol 20xx/xxx). If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Telephone: +61 2 6125 3427
Email: Human.Ethics.Officer@anu.edu.au

## Informed Consent for adult household member (Form 1a)

**WRITTEN CONSENT FOR PARTICIPANTS**

**Eliminating the major Helminth Neglected Tropical Diseases from the Lower Mekong Basin**

**The Magic Glasses E-joint Research Program**

 *(For adult household member)*

I have read and understood the Information Sheet you have given me about the research project, and I have had any questions and concerns about the project (listed here

 )
addressed to my satisfaction.

I agree to participate in the project. YES ☐ NO [ ]

I agree to this interview being audio-recorded YES ☐ NO [ ]

I agree to be identified in the following way within research outputs: YES ☐ NO [ ]

Signature: …………………………………………….

Date: ………………………………………………….

## Parental Informed Consent for ages 5-17 (Form 1b)

**WRITTEN CONSENT FOR PARTICIPANTS**

**Eliminating the major Helminth Neglected Tropical Diseases from the Lower Mekong Basin**

**The Magic Glasses E-joint Research Program**

*(Parental Consent for aged 5-17 years)*

I have read and understood the Information Sheet you have given me about the research project, and I have had any questions and concerns about the project (listed here

 )
addressed to my satisfaction.

I agree to allow my child to participate in the project YES ☐ NO [ ]

I agree to allow my child to be identified in the following way within research outputs:

 YES ☐ NO [ ]

Signature: …………………………………………….

Date: ………………………………………………….

## Information sheet (for 12 -17 years old)

**Participant Information Sheet**

**Eliminating the major Helminth Neglected Tropical Diseases from the Lower Mekong Basin**

**The Magic Glasses E-joint Research Program**

***(For children 12-17 years old)***

My name is \_\_\_\_\_\_\_\_\_\_\_\_ and I work at (place holder). My team are testing a health promotion/intervention package to help the community learn more about intestinal worms and liver fluke infections. These infections are some of the most important public health problems in our community. We want to help stop it spreading.

To assess whether the health promotion/intervention package we developed is effective in lowering the intestinal worm and liver fluke infections, we will ask your participation to do the following if you agree.

|  |  |
| --- | --- |
| **Activities** | **Schedule of data collection** |
| 1. Collect two stool samples (all household members aged ≥5 years) | These will be done upon joining the study and at follow-up. |
| 2. Obtain a very small amount of blood through finger prick to determine if you have anemia. Anemia is a condition that develops when your blood lacks enough healthy red blood cells or hemoglobin. This can cause paleness, tiredness or fatigue, and weakness.  |
| 3. Height and weight measurements  |
| 4. Nutritional assessment |
| 5. Answer a questionnaire about what you know or feel about intestinal worms and liver fluke and the things that you do to prevent these infections.  |
| 6. Provision of medicine for intestinal worms (Albendazole) and liver fluke infections (Praziquantel)  | This will be done at the start of the project. We will also provide medicine at the end of the project if you still have intestinal worm/Ov infections to help cure it.  |

The information you give us will help us know how effective the health promotion/intervention package is. This will then help prevent the spread of infection in our country.

You don’t have to do this work. If you don’t want to take part, please tell parents. That is not a problem. You can also change your mind at any time. You can answer some questions but not others. Nothing bad will happen if you don’t want to be part of this work.

If you have any questions you can ask me or parent. You can ask at any time. Thank you for reading this.

## Informed Assent (Form 1c)

WRITTEN ASSENT for Participants

(For children aged 12-17 years)

**Eliminating the major Helminth Neglected Tropical Diseases from the Lower Mekong Basin**

**The Magic Glasses E-joint Research Program**

I have read and understood the Information Sheet you have given me about the research project [*or that the research staff have read this form aloud to me*], and I have had any questions and concerns about the project (listed here

 )
addressed to my satisfaction.

I agree to participate in the project. YES ☐ NO [ ]

I agree to let you make a recording of what I say /or being audio-recorded YES ☐ NO [ ]

Name of Child: …………………………………………….

Date: ………………………………………………….