COVER SHEET FOR THERAPEUTIC EFFICACY TEST PROTOCOL

Title	Evaluation of the efficacy and safety of Artemether +Lumefantrine (Coartem®) with low-dose Primaquine for the treatment of uncomplicated *Plasmodium falciparum* and *Plasmodium* vivax malaria in three sites of Savanakhet, Salavanh, and Attopue province, Lao PDR
Study site(s)	Site 1: there are 5 district hospitals involved such as Phin, Sepon, Nong, Vilabury, and Thapangtong districts, Savanakhet province Treatments tested: Artemether + Lumefantrine Site 2: All 5 health facility catchment areas named as provincial and Military hospital, Taoi, Toumlan, Samouai district, Salavanh province Treatments tested: Artemether +Lumefantrine Site 5: Military hospital, Phouvong, Sansay, Sanamsay, and Saysetha districts, Attopue province (4 districts and 1 military hospitals) Treatments tested: Artemether +Lumefantrine
Protocol submission date	28 April 2022
Protocol number	Lao 01/2022
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Planned study dates	From June 2022 to June 2023
Sponsor	Ministry of Health Vientiane, Lao PDR

SYNOPSIS

Title: Evaluation of the efficacy and safety of Artemether+ Lumefantrine (Coartem®) with low-dose Primaquine for the treatment of uncomplicated *Plasmodium falciparum* and *Plasmodium* vivax malaria in three sites of Savanakhet, Salavanh, and Attopue province, Lao PDR.

Purpose: To assess the efficacy of current first line treatment policy

Objective: To assess the efficacy and safety of artemether-lumefantrine for the treatment of uncomplicated *P. falciparum* and *P. vivax* malaria infections.

Study Sites: Three provinces of Savanakhet (5 districts of Phin, Sepon, Nong, Vilabury, and Thapangtong), Salavanh (2 provincial hospitals (public and Military) and 3 districts of Samouai, Taoi and Toumlan), and Attopue (4 districts of Phouvong, Sansay, Sanamsay, and Saysetha; and 1 Military hospital)

Study Period: From August 2022 to September 2023

Study Design: This surveillance study is a one arm prospective study

Patient population: Febrile patients aged between 6 months and 60, with confirmed uncomplicated *P. falciparum and P. vivax* infection, except females aged 12-18 years old, as it is culturally sensitive to request pregnancy test for young unmarried women.

Sample Size: Total of **300** patients to be enrolled **150** Pf and 150 Pv cases. Each study site/province will recruit 100 cases, in which 50 cases maximum of Pf and 50 cases maximum of Pv)

Treatment(s) and follow-up: Artemether-lumefantrine drug combination (Artemether 20mg / lumefantrine 120 mg per tablet), twice a day will be administered over 3 days according to body weight to a total of 6 doses. Primaquine will be administered as a single 15-mg adult dose (0.25 mg base/kg) on day 0 for uncomplicated *P. falciparum* cases, and once daily (0.25 base/kg) for 14 days for Glucose-6-phosphate dehydrogenase (G6PD) normal or weekly dose (0.75 base/kg) for 8 weeks for G6PD deficient *P. vivax* cases. The correct drug dosage will be determined from the dosing chart (Appendix 3). Clinical and parasitological parameters will be monitored over a 28-day follow-up period to evaluate drug efficacy.

Primary endpoints: The proportion of patients with early treatment failure, late clinical failure, late parasitological failure or an adequate clinical and parasitological response as indicators of efficacy. Recrudescence will be distinguished from re-infection by polymerase chain reaction (PCR) analysis.

Secondary endpoints: The frequency and nature of adverse events

Exploratory endpoints: to determine the polymorphism of molecular markers for artemisinin resistance.

Service precautions:

Trained health workers for TES purpose apply key IPC principles to consider and the precautions to take for safely delivering service during the context of COVID-19 to reduce the risk of transmission; Standard precautions to be applied during screening the malaria suspected case for recruitment, treatment, and follow up the cases. They are (1) prepare a clean, hygienic and well ventilated room/area with adequate spaces for physical distancing; and put up visual reminders emphasizing hand hygiene, safe use of medical masks, respiratory hygiene, and other IPC measures; (2) ensure of adequate number of hand hygiene stations in entrance/exist areas to support appropriate hand hygiene for the service clients; (3) follow screening policies for COVID-19 signs and symptoms for all individuals arriving with suspected malaria symptoms; and (4) Practice at least 1 metre physical distance between all individuals during service;

1. BACKGROUND

In Lao PDR, the current guidelines for malaria treatment (developed in 2014 and updated in 2017) recommends for the first-line treatment for uncomplicated *P. falciparum* malaria artemether-lumefantine (Coartem®) twice a day for 3 days + single low dose PQ and for *P. vivax* malaria, is also Artemether-lumefantrine for 3 days + PQ (low dose) for 14 days for G6PD normal patients (or PQ 0.75 mg/kg bw/week, weekly dose for 8 weeks for G6PD deficient patients). The second-line treatment is oral quinine and doxycyline tablets for 7 days. Parenteral artesunate is recommended for severe and complicated *P. falciparum* malaria and oral Chloroquine + Primaquine (daily dose for 14 days or weekly dose for 8 weeks) is recommended for uncomplicated *P. vivax.* However, the guideline is now under revision to change second line treatment to be an ACT drug instead. The revision is expected to be completed in 2022.

Lao PDR conducted TES to monitor efficacy of Chloroquine during 2001 to 2002 in northern and southern Lao PDR (Luangnamtha and Attopue province, respectively) with results showing 52.8% treatment failure of *P. falciparum*. Then the MOH conducted a TES using Pyrimethamine-sulfadoxine in Luangnamtha province that showed 18.7% total failures. In 2003, in-vivo studies in Luangnamtha Province with artemether-lumefantine (AL) showed 6.4% total failures (PCR corrected). In 2007 and 2010, there were no failures in Khammoune Province. From 2012 to 2015, TES in Salavanh, Champasak, Sekong and Attopue provinces were carried out with results showing ACPR at 98%, 90%, 86% and 100%, respectively. Day 3 positivity ranged from 0 to 22%, with the highest in Champasak and Sekong at 22% and 20%, respectively. Later in 2016-2017, results of DHA-PIP efficacy study in Champasack Province showed 26% D3 (+), 44% treatment failures, and 83% of K13 mutations in D0. Resistance to piperaquine (pfpm2 molecular marker) increased to 60%, with the spread of ACT failures in the Greater Mekong Sub-region beyond Cambodia. The efficacy level of DHA-PIP in Cambodia had gradually decreased to as low as 37.5% in Siam Reap and 60% in StungTreng (which borders Champasak) in 2014.

In summary, during 2003-2011, there were 14 TES conducted to monitor efficacy of Artemether-Lumefantrine ONLY in northern (Luangnamtha, Luangprabang, Khammuane) and southern provinces (Savanakhet, Salavanh, Attopue) of Lao PDR and ACPR ranged from 93-100%. In the last 4 years of 2013-2017, efficacy of AL declined in Champasack and Sekong provinces to below 90% ACPR. Delayed parasite clearance (> 10% D3+) was reported highest in Champasack (22%), Salavanh (20%) and Sekong (14%). Most importantly, K13 mutations ranged from 20% to 87% in these provinces.

In 2017, the National Programme collected 100 dried blood spots (DBS) from *Pf* confirmed cases in Nong district of Savanakhet Province (sharing border to central Vietnam), for molecular testing to certify malaria outbreak. The dbs samples tested at the Institute Pasteur du Laos (IPL) succeeded in extracting DNA for sequencing from 69 samples. Results indicated that there were no mutations in the K13 gene in any of the tested samples.

From 2019 to 2020, the CMPE conducted TES for artemether-lumefantrine (AL) in the three southern provinces of Champasak, Salavanh and Savannakhet. AL demonstrated 96.3% efficacy for *P. falciparum* cases and 100% for *P. vivax* cases in Savannaket, whereas in Champasak and Salavanh, AL demonstrated 100% efficacy for both *P. falciparum* and *P. vivax* cases. Therefore, AL TES results from 2020 indicate its continued effectiveness for treating *P. falciparum* and *P. vivax* malaria; 78 *Pf* blood samples were collected on day 0 for *in vitro* drug susceptibility testing in order to evaluate *in vitro* susceptibility of *P. falciparum* isolates to Artemether-Lumefantrine. The *in vitro* drug susceptibility test will be performed in Pasteur Institute of Cambodia pending transport of samples for analysis hampered by COVID-19 transport restrictions. Molecular markers indicate that K13 mutations have continued to decline on day zero, and there is a limited number of C580Y except in Champassak province. This suggests artemisinin resistance is waning. The molecular marker data showed that there were no indicators of mefloquine resistance. Plasmepsin2 copy number is also decreasing, indicating a reversal of piperaquine (PPQ) resistance. ASMQ and AS-PY remain efficacious. Artemether-lumefantrine (AL) showed an increased efficacy in 2020 when compared to 2019.

In 2021, the WHO Ethics Review Committee (ERC) approved TES for *P. falciparum* and *P. vivax* in three sites in Savanakhet, Sekong and Attopue. However, COVID-19 restrictions led to delays in the implementation of the TES planned for 2021 and have to extended to April 2022. Data analysis result is pending.

As per the current evidence base, there is a risk that the efficacy of AL may decline in some areas of Lao PDR, but probably not in all provinces. To further strengthen the evidence available to the country and to assist in treatment policy making decisions, the efficacy of the current first line treatment artemether-lumefantine (AL, Coartem®) against *P. falciparum* and *P.vivax* infections will be assessed again in several districts of the southern provinces of Savanakhet, Salavanh and Attopue.

2. OBJECTIVES

The general objective of this study is to assess the therapeutic efficacy and safety of drug combination artemether – lumefantine for the treatment of uncomplicated *P. falciparum* and *P. vivax* malaria in several districts of the three provinces of Savanakhet, Salavanh and Attopue, Lao PDR.

The primary objectives are:

- to measure the clinical and parasitological efficacy of name of the antimalarial drug(s) or drug combination(s) in patients aged between minimum age months/years and maximum age months/years, suffering from uncomplicated falciparum malaria, by determining the proportion with early treatment failure, late clinical failure, late parasitological failure or an adequate clinical and parasitological response as indicators of efficacy;
- to differentiate recrudescence from new infection by polymerase chain reaction (PCR) analysis.

The secondary objectives are:

- to evaluate the incidence of adverse events; and

The optional exploratory objectives are:

- to determine the polymorphism of molecular markers for name of the antimalarial drug(s) resistance.

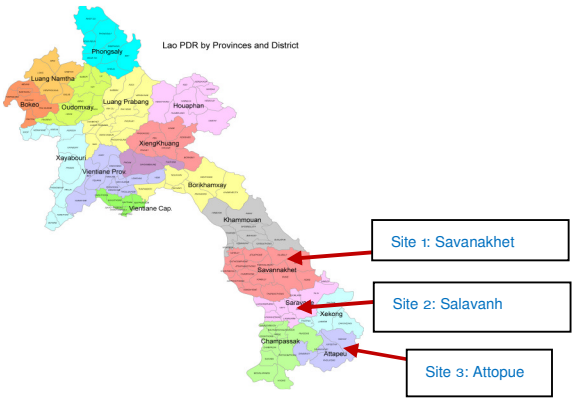
3. METHODS

3.1 Study design

This surveillance study is a one-arm prospective evaluation of clinical and parasitological responses to directly observed treatment for uncomplicated malaria.[1,2] People with uncomplicated malaria who meet the study inclusion criteria will be enrolled, treated on site with the ACT artemether-lumefantrine for uncomplicated *P. falciparum* and *P. vivax* malaria and monitored for 28 days. The follow-up will consist of a fixed schedule of check-up visits and corresponding clinical and laboratory examinations. Based on the results of these assessments, the patients will be classified as having therapeutic failure (early or late) or an adequate response. The proportion of patients experiencing therapeutic failure during the follow-up period will be used to estimate the efficacy of the study drug. PCR analysis will be used to distinguish between a true recrudescence/relapse due to treatment failure and episodes of reinfection.

3.2 Study site

Three sites in southern Laos have been selected for the TES, Savanakhet, Salavanh, and Attopue provinces (see Map 1). Targeted districts in these provinces had been selected as TES sites in according to malaria incidence distribution during 2020-2021.



3.2.1 Savannakhet province:

The study will be conducted in 5 of 15 districts in the province. They are Phin, Sepon, Nong, Thapangthong, and Vilaboury in Savanakhet Province, Lao PDR.

In 2021, There were **5** malaria hot spots district in Nong, Sepon, Thapangthong, Vilaboury, and Phin district. However, Nong district district, which shares border with Samuai district-Salavanh province was highlighted as biggest hot spot of the province. Malaria case was reported one-fold compared to year 2020, from 403 cases to 856 cases. *Plasmodium falciparum* (*P.f*)cases in 2021 was highly increased 100% due to numbers of outbreak occurred during the year accounted to 81.3% of total malaria species reported. Table 1 was highlighted cluster of the province. Three to ten folds increasing of *P.f* species in 2021 also noticed in Sepond and Phin district, where are adjacent to Nong district. Transmission originally occurred in forest areas then spread out in the villages. Other factors to support people at-risk of malaria infection is related to their daily work and cultivation behaviour in forest/forest fringe. Overall, malaria testing was maintained high for both 2020 and 2021 due to additional malaria screening in malaria outbreak response areas with testing positive rate ranged from 0.6-2%.

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[1] WHO. *Assessment and monitoring of antimalarial drug efficacy for the treatment of uncomplicated falciparum malaria*. Geneva, World Health Organization, 2003 (WHO/RBM/HTM/2003.50) (http://www.who.int/malaria/resistance).

[2] WHO. *Method for surveillance of antimalarial drug efficacy*. Geneva, World Health Organization, 2009 (http://www.who.int/malaria/resistance).

Table 1: **Malaria case reported by health facility catchment areas of Savannakhet province, 2020-2021**

HFCA	Malaria tested		Confirmed case 2020			Confirmed case 2021		
	2020	2021	P.f	P.v	Mix	P.f	P.v	Mix
1304 Phin	6,384	12,193	3	3	0	49	0	0
1305 Sepon	19,565	22,276	94	8	0	296	11	0
1306 Nong	22,896	34,462	189	41	1	373	79	4
1307 Thapangthong	7,896	12,722	3	12	0	1	6	0
1308 Songkhone	2,032	3,018	0	2	0	0	0	0
1309 Champhone	2,605	3,518	0	3	0	0	0	1
1310 Sonbury	6,303	7,238	0	0	0	0	2	0
1311 Xaybury	1,223	1,753	0	1	0	0	2	0
1312 Vilabury	2,882	4,254	17	0	0	10	0	00
1313 Atsaphone	1,791	2,633	0	0	0	0	3	0
1314 Xayphouthong	818	1,688	0	0	0	0	0	0
1315 Phalanxay	4,084	4,656	2	0	0	0	0	0
Kaison	3,593	484	0	0	0	0	1	0
Outhoumphone	7,318	5,975	18	2	0	0	2	0
Atsaphangthong	4,039	6,853	0	0	0	0	0	0
Provincial hospital	890	4,837	2	2	0	1	0	0
Total	**94,319**	**128,560**	**328**	**74**	**1**	**732**	**99**	**5**

3.2.2 Salavanh:

The study will be conducted in 5 health facilities, in which two are the provincial hospital and military hospital, and 3 district hospitals in (1) Taoi, (2) Toumlan, and (3) Samouay. In 2020, a total of 317 malaria confirmed were cases reported in this province and increased to 502 cases in 2021. Malaria vivax was dominated, accounting for 95.6% of the total cases in the entire the province. In the three targeted districts of Salavanh, Taoi, and Toumlan reported malaria case up to 93% of total case for 2021, and 96.7% was infection of *P.vivax* (see table 2). Few years ago, there was over 90% of Pv case reported in this Samouay district, but less in year 2020 and 2021. However, since the district is neighboring to the other targeted endemic district, it is therefore, Samouay is one of target district to be monitored of the ACT efficacy.

Table 2: Malaria case reported by health facility catchment areas of Salavan province, 2020-2021

Organization unit / Data	# Tested		Case detected in 2020			Case detected in 2021		
	2020	2021	Pf	Pv	Mix	Pf	Pv	Mix
PH Saravane	2,644	1,601	3	10	0	0	7	0
1401 DHO Saravane	11,933	17,947	2	30	0	0	63	0
1402 DHO Taoi	14,132	19,627	57	90	0	15	302	0
1403 DHO Toumlan	6,425	10,831	3	17	2	0	88	0
1404 DHO Lakhonepheng	5,300	8,146	0	16	1	0	7	0
1405 DHO Vapy	6,204	6,416	1	3	1	3	5	1
1406 DHO Khongxedone	6,732	8,887	4	8	0	0	0	0
1407 DHO Laongam	5,464	8,312	0	4	0	0	5	0
1408 DHO Samouay	30,971	18,286	5	60	0	3	0	0
Total	**89,805**	**100,053**	**75**	**238**	**4**	**21**	**480**	**1**

3.2.3 Attopue province:

Attopue province is in the southern-most part of the country with one international checkpoint that links the province to southern Vietnam (Gia Lai, Kon Tum and Ho Chi Minh City). Vietnamese people come and go to Attopue for business and plantation purposes. The original forest cover in this province is high, so rich in forest products that draw people and generate income from it. It is linked to peoples' behavior, as majority access the forest for daily income. Other risk behaviors are related to cultivation practices, with entire families staying overnight in temporary huts three months at a time to harvest their agricultural produce. In addition, many villages are located right in the forest fringes hence the risk of malaria transmission all year round. With expansion of agricultural programme such as casava, banana, rubber plantation and other hydro-power dam construction projects, this leads to more labors mobilization that creates internal mobilization

of people from other provinces as well as local residence in the areas. This is assuming as key factor that create more malaria-risk exposure.

These days, Attopue province is highlighted as top high malaria case reported province in the country with 1,577 and 1512 malaria cases reported in 2020 and 2021 respectively. Ratio of malaria falciparum and vivax is 1:2 in 2021; Compared to 2020, confirmed malaria falciparum reported in 2021 is reduced almost 50%, but still high compare to other provinces (Table 3); One dead case due to malaria cerebral had been reported from this Phouvong district. The outbreak occurred throughout the year with clusters in three districts of Phouvong, Sanxay, and Saysetha districts. Since the districts are not far from urban town of the province, numbers of malaria case also detected in provincial hospital for both public and military.

Effort from the province and National programme for outbreak response was huge and consistently, however, the case still detected in other areas of the districts. So, the four of total five most malaria endemic districts and 1 military hospital in this province will be targeted for TES.

Table 3: Malaria case reported by health facility catchment areas of Attopue province, 2020-2021

HFs	Malaria tested		# Pf case		# Pv case		# Mix case	
	2020	2021	2020	2021	2020	2021	2020	2021
Provincial Hospital	1,753	822	18	14	29	41	0	3
Saysetha district	18,544	19,930	56	36	118	251	2	3
Samakhixay District	4,963	8,586	23	6	11	1	0	1
Sanamsay District	7,921	13,181	6	5	44	105	0	0
Sansay District	17,510	18,432	207	138	153	212	7	5
Phouvong District	23,664	28,823	557	265	311	387	13	6
Military hospital	1,740	825	1	3	21	30	0	0
Total	**76,095**	**90,599**	**868**	**467**	**687**	**1,027**	**22**	**18**

3.3 Study population

The population will consist of patients with uncomplicated *P. falciparum* and *P. vivax* malaria attending the study health clinic who are aged 6 months up to 60 years old, except females aged 12-18 years old who will be excluded. All adult patients will sign an informed consent form for participation. Parents or guardians will give informed consent on behalf of children. Children over 12 years of age will sign an informed assent form.

3.4 Timing and duration of study

The study will be conducted over a 13-month period, from August 2021 to August 2022

3.5 Inclusion criteria

- aged 6 months up to 60 years old;
- mono-infection with *P. falciparum* and *P. vivax* confirmed by positive blood smear (no mixed infection);
    - *P. falciparum* parasitaemia of 250-100,000/µl asexual forms;
    - *P. vivax* parasitaemia of 250-60,000/µl asexual forms
- presence of axillary temperature ≥ 37.5 °C or history of fever during the past 24 h;
- ability to swallow oral medication;
- ability and willingness to comply with the study protocol for the duration of the study and to comply with the study visit schedule; and
- Informed consent from the patient or from a parent or guardian in the case of children.
- informed assent from any minor participant aged from 12 to 18 years; and
- consent for pregnancy testing from female of child-bearing age (defined as age > 12 years and sexually active).

3.6 Exclusion criteria

- presence of general danger signs in children aged under 5 years or signs of severe falciparum malaria according to the definitions of WHO (Appendix 1);
- mixed or mono-infection with another Plasmodium species detected by microscopy;
- presence of severe malnutrition (defined as a child whose growth standard is below –3 z-score, has symmetrical

oedema involving at least the feet or has a mid-upper arm circumference < 110 mm);

- presence of febrile conditions due to diseases other than malaria (e.g. measles, acute lower respiratory tract infection, severe diarrhea with dehydration) or other known underlying chronic or severe diseases (e.g. cardiac, renal and hepatic diseases, HIV/AIDS);
- regular medication, which may interfere with antimalarial pharmacokinetics;
- history of hypersensitivity reactions or contraindications to any of the medicine(s) being tested or used as alternative treatment(s);
- Women age 12-18 years old
- a positive pregnancy test or lactating
- Unable to or unwilling to take contraceptives for pregnancy negative married women of child- bearing age.

3.7 Loss to follow-up

Loss to follow-up occurs when, despite all reasonable efforts, an enrolled patient does not attend the scheduled visits and cannot be found. No treatment outcome will be assigned to these patients. Every effort must be made to schedule a follow-up visit for patients who fail to return to the study site, especially during but also after administration of the study drug. These patients will be classified as lost to follow-up and censored or excluded from the analysis. Patients who are lost to follow-up but who subsequently return to the study site before day 28 will not be turned away and will be encouraged to return for check-up visits. The principal investigator will decide whether the patient is to be classified as lost to follow-up on the basis of his or her history or is to be maintained for the analysis.

3.8 Patient discontinuation or protocol violation

Study patients who meet any of the following criteria will be classified as withdrawn.

- Withdrawal of consent. A patient may withdraw consent at any time, without prejudice for further follow-up or treatment at the study site.
- failure to complete treatment, due to:
    - Persistent vomiting of the treatment. A patient who vomits the study medication twice will be withdrawn from the study and given rescue treatment.
    - failure to attend the scheduled visits during the first 3 days; or
    - Serious adverse events necessitating termination of treatment before the full course is completed. A patient can be discontinued from the study if the principal investigator decides so due to an adverse event of adequate nature or intensity. In this case, information on the adverse event and symptomatic treatment given must be recorded on a case report form. If the adverse event is serious, the principal investigator must notify the sponsor or its designee immediately and follow the reporting procedures described in section 5.3.
- enrolment violation:
    - severe malaria on day 0; or
    - erroneous inclusion of a patient who does not meet the inclusion criteria.
- voluntary protocol violation: self- or third-party administration of antimalarial drug (or antibiotics with antimalarial activity) (Appendix 2);
- involuntary protocol violation:
    - occurrence during follow-up of concomitant disease that would interfere with a clear classification of the treatment outcome;
    - detection of mono-infection with another malaria species during follow-up; or
    - misclassification of a patient due to a laboratory error (parasitaemia), leading to administration of rescue treatment.

Patients who are withdrawn will nevertheless be followed up until recovery or the end of follow-up, if possible; however, no treatment outcome will be assigned to these patients, and they will be censored or excluded from the analysis. The reasons for discontinuation or protocol violation will be recorded on the case report form.

4. TREATMENT

4.1 Antimalarial treatment

Artemether-lumefantrine drug combination will be administered for 3 days according to body weight for the treatment of uncomplicated *P. falciparum* and *P. vivax* malaria. Tablets of Artemether 20mg – lumefantrine 120 mg will be obtained from Novartis Pharmaceuticals Istanbul, Turkey for Novartis Pharma AG, Basle, Switzerland under licence from the PRC. The correct drug dosage will be determined from the dosing chart (Appendix 3).

Primaquine will be administered as a single 15-mg adult dose (0.25 mg base/kg) on day 0 for *P. falciparum* cases.

For G6PD normal *P. vivax* cases, once daily (0.25 base/kg) for 14 days will be given. For patients with G6PD deficiency, weekly dose (0.75 mg/kg bw/week) for 8 weeks will be prescribed after completion of day 28 following up.

Doses of AL medicine will be administered under the supervision of a qualified and trained physician designated by the principal investigator (patient will be admitted and hospitalize for three nights to ensure of supervised treatment and parasitemia following up). The study patients will be observed for 30 min after medicine administration for adverse reactions or vomiting. Any patient who vomits during this observation period will be re-treated with the same dose of medicine and observed for an additional 30 min. If the patient vomits again, he or she will be withdrawn and offered rescue therapy. Study patients will be required to return to the clinic for each dosing day, with the second dosing administered at home by a trained health worker.

4.2 Concomitant treatment and medication that should not be used

Fever over 38 °C can be treated with paracetamol or acetaminophen. Parents or guardians will be instructed in the use of tepid sponging for children under 5 years of age.

Prior treatment with antimalarial drugs will not be considered an exclusion criterion; however, during follow-up, if infections other than malaria require the administration of medicines with antimalarial activity, the patient will be withdrawn from the study. Patients given tetracycline as an eye ointment will not be excluded (Appendix 2). Patients will be withdrawn from the study in the case of self-medication or if an antimalarial drug or an antibiotic with antimalarial activity is administered by a third party.

Adverse events requiring treatment can be treated according to local practice. If there is a clinical indication for any additional medication during the course of the study, including medication given to treat an adverse event related to the study medicine, the name of the medicine, the dosage and the date and time of administration must be recorded on the case report form.

The use of herbal remedies during the study should be avoided, and participants should be encouraged to return to the study site for treatment if they feel unwell. If any herbal remedies are taken during the study, this should be captured on the case report form, under ‘study medication administration’.

4.3 Rescue treatment

Any patient with signs of severe or complicated malaria or vomiting twice will be hospitalized and will receive parenteral therapy with artesunate intravenous injection: first dose 2.4 mg/kg; repeated after 12 hours with 2.4 mg/kg and 24 hours with 2.4 mg/kg, followed by 2.4 mg/kg daily until patient can take oral meds for a full 5 day course of treatment and relevant supportive treatment according to national treatment guidelines. The case will be then withdrawn from the study.

Women who are found to be pregnant at enrolment will be treated with quinine 10 mg/kg eight hourly for seven days during the first trimester; during the second and third trimesters, Artemether-lumefantrine drug combination will be used according to national treatment guidelines.

If a patient meets one of the criteria for therapeutic failure, he or she will receive the second-line treatment: for falciparum malaria, quinine plus doxycycline given for 7 days according to current national recommendation. If the patient is re-infected with another malaria species, he or she will receive antimalarial drug(s) according to current national recommendations.

5. EVALUATION CRITERIA

The study end-point is the classification assigned to a patient. Valid study end-points include: treatment failure, completion of the follow-up period without treatment failure, loss to follow-up, withdrawal from study, and protocol violation. At all times, the well-being of the patient will take priority over his or her continuation in the study.

5.1 Efficacy and safety evaluation

5.1.1 Classification of treatment outcomes

Treatment outcomes will be classified on the basis of an assessment of the parasitological and clinical outcome of antimalarial treatment according to the latest WHO guidelines.[3] Thus, all patients will be classified as having early treatment failure, late clinical failure, late parasitological failure or an adequate clinical and parasitological response, as defined in Appendix 4.

As parasitological cure is the goal of antimalarial therapy, all study patients who show treatment failure will be given rescue treatment. Follow-up will continue until recovery. The results from these patients do not need to be recorded systematically for the purpose of the surveillance study.

5.1.2 Safety end-points

The incidence of any adverse event will be documented. All patients will be asked routinely about previous symptoms and about symptoms that have emerged since the previous follow-up visit. When clinically indicated, patients will be evaluated and treated appropriately. All adverse events will be recorded on the case report form. Serious adverse events (see definitions in 5.3) must be reported to CMPE and record immediately in the pharmaco-vigilance data base of Food and Drug Department, Ministry of Health.

5.2 Clinical evaluation

All patients will be evaluated clinically as described below.

5.2.1 Physical examination

A standard physical examination will be performed at baseline (day 0 before dosing) and on days 1, 2, 3, 7, 14, 21, 28. A complete medical history, demographic information and contact details will be taken at baseline.

5.2.2 Body weight

Body weight will be recorded on day 0 to the nearest kilogram on a Salter scale or on a hanging scale for young children. The scales will be properly calibrated. Patients should not wear excessive clothing while being weighed as this can overestimate their true weight. All young children should only wear undergarments while being weighed. The screening weight will be used to satisfy the inclusion or exclusion for nutrition status as well as to calculate the dose (number of tablets) to be administered. The reliability of the scales will be verified before the study begins and checked at regular intervals.

The circumference of the left mid-upper arm will be measured, at the mid-point between the elbow and the shoulder, and will be recorded to the nearest 0.2 cm.

Oedema will be assessed by thumb pressure for 3 second on the dorsal surface of both feet.

5.2.3 Body temperature

Axillary temperature will be measured at baseline (day 0 before dosing) and on days 1, 2, 3, 7, 14, 21, 28. Temperature will be measured with a thermometer that has a precision of 0.1 °C. Temperature will also be measured as clinically indicated. If the result is < 36.0 °C, the measurement will be repeated. The same route should be used throughout the study.

The quality of the temperature-taking technique and the thermometers should be assessed regularly. Thermometers should be tested in a water-bath of known temperature before the study begins and at regular intervals thereafter.

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[3] WHO. *Susceptibility of* Plasmodium falciparum *to antimalarial drugs. Report on global monitoring 1996–2004*. Geneva, World Health Organization, 2005 (WHO/HTM/MAL/2005.110) (http://www.who.int/malaria/resistance).

5.2.4 Microscopic blood examination

Blood sample in amount 1 µl will be collected from finger bricking to create thick and thin blood films for parasite counts should be obtained and examined at screening on day 0 to confirm adherence to the inclusion and exclusion criteria. Thick blood films will be also examined on days 1, 2, 3, 7, 14, 21, 28 or on any other day if the patient returns spontaneously and parasitological reassessment is required. Specimens will be labelled anonymously (screening number or study number, day of follow-up, date).

A fresh Giemsa stain dilution will be prepared at least once a day and possibly more often, depending on the number of slides to be processed. Giemsa-stained thick and thin blood films will be examined at a magnification of 1000× to identify the parasite species and to determine the parasite density.

Three blood slides per patient will be obtained: two thick blood smears and one thin blood smear. One slide will then be stained rapidly (10% Giemsa for 10–15 min) for initial screening, while the others will be retained. If the patient is subsequently enrolled, the second slide will be stained more carefully (e.g. 2.5–3% Giemsa for 45–60 min), and slower staining will also be used for all slides obtained at follow-up visits. The study number of the patient, the date and the day of follow-up will be recorded either on the frosted edge of the slide or on the glass with a permanent glass pen.

The thick blood smear for initial screening will be used to count the numbers of asexual parasites and white blood cells in a limited number of microscopic fields. The adequate parasitaemia for enrolment is at least one parasite for every six white blood cells, corresponding to approximately 1000 asexual parasites per microlitre, for low transmission areas like Laos.

The second blood smear will be used to calculate the parasite density, by counting the number of asexual parasites in a set number of white blood cells (typically 200) with a hand tally counter. Once a field has been started, it must be counted to completion; the final number of white blood cells will therefore rarely be exactly 200. If more than 500 parasites have been counted before 200 white blood cells have been reached, the count will be stopped after the reading of the last field has been completed. Parasite density, expressed as the number of asexual parasites per µl of blood, will be calculated by dividing the number of asexual parasites by the number of white blood cells counted and then multiplying by an assumed white blood cell density (typically 6000 per µl).

$$\text{Parasite density (per µl)} = \frac{\text{number of parasites counted} \times (6000)}{\text{Number of leukocytes counted}}$$

The same technique will be used to establish the parasite count on each subsequent blood film. When the number of asexual parasites is less than 10 per 200 white blood cells in follow-up smears, counting will be done against at least 500 white blood cells (i.e. to completion of the field in which the 500th white blood cell is counted). A blood slide will be considered negative when examination of 1000 white blood cells reveals no asexual parasites. The presence of gametocytes on an enrolment or follow-up slide will be noted, but this information will not contribute to basic evaluation.

In addition, 100 fields of the second-thick film will be examined to exclude mixed infections; in case of any doubt, the thin film will be examined for confirmation. If examination of the thin film is not conclusive, the patient will be excluded from the analysis after complete treatment and follow-up.

Two qualified microscopists will read all the slides independently, and parasite densities will be calculated by averaging the two counts. Blood smears with discordant results (differences between the two microscopists in species diagnosis, in parasite density of > 50% or in the presence of parasites) will be re-examined by a third, independent microscopist, and parasite density will be calculated by averaging the two closest counts.

5.2.5 Genotyping of malaria parasites

In order to differentiate a recrudescence (same parasite strain) from a newly acquired infection (different parasite strain), a genotype analysis will be conducted. This is based on the extensive genetic diversity among the malaria parasite genes *msp1*, *msp2* and *glurp*.[4] The genotypic profiles of pre- and post-parasite strains are compared.

In order to minimize discomfort to the patient due to repeated finger pricks, two to three drops of blood will be collected on filter paper (Whatman 3 MM filter paper) from each patient at inclusion (enrolment). A second specimen will be collected only from patients presenting with treatment failure on or after day 7.

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[4] WHO. *Methods and techniques for clinical trials on antimalarial drug efficacy: genotyping to identify parasite populations.* Geneva, World Health Organization, 2008 (http://www.who.int/malaria/resistance).

Specimens will be labelled anonymously (study number, day of follow-up, date), kept in individual plastic bags with desiccant pouches and protected from light, humidity and extreme temperature until analysed. When these conditions cannot be achieved, for example in extremely humid environments where air-conditioning is not available, storage in a refrigerator or freezer may be considered, but great care must be taken to protect samples from frost and moisture. Filter papers sample will be sent to laboratory of Pasteur Institute of Cambodia for PCR test. Paired filter papers will be used for parasite DNA extraction and genotyping only in cases of treatment failure. Unused filter papers will be destroyed immediately after the study.

5.2.6 Pregnancy test

Female patients of age 12-18 will be excluded from this study. Female patients of child-bearing age, defined as those who menstruate and are aged over 18 years, will be asked to take a urine pregnancy test before enrolment in the study, because AL is contraindicated during the first trimester. They will also be asked to take a urine pregnancy test on day 28 or on early withdrawal from the study.

Female participants of child-bearing age, defined as those who menstruate and are aged over 18 years, and who are sexually active should use barrier contraceptive devices for the duration of the study. The contraceptive will be provided by the investigator or study team at the time informed consent is obtained, with appropriate counselling about the risks of becoming pregnant and exposing the fetus to the study medicines.

5.2.7 Molecular markers for antimalarial drug resistance

Two to three drops of blood will be collected on filter paper (Whatman 3 MM) on day 0 (and day of failure) to study the polymorphism or copy number of *pfmdr1, pfatp6* and *pfcrt* gene, which are considered as markers of resistance to artemether-lumefantrine. The technique used will be polymerase chain reaction PCR. The test will be done at the laboratory of Pasteur Institute, Cambodia. Specimens will be labelled anonymously (study number, day of follow-up, date), kept in individual plastic bags with desiccant pouches and protected from light, humidity and extreme temperature until analysed.

5.2.8 Glucose-6-phosphote dehydrogenase deficiency

Glucose-6-phosphote dehydrogenase deficiency will be determined at admission by using Point-of-Care Rapid Diagnostic Test kit (POC RDT). The test will be done in the TES-targeted district/provincial hospitals. A drop of blood from the left 4th pricked finger will be collected and drop into sample hole of the POC RDT. Reading test result will be done in 10 minutes after adding buffer to support registration decision and appropriate treatment prescription.

5.2.9 In vitro susceptibility of *P. falciparum* isolates

A blood sample of 5 ml for in vitro drug susceptibility testing will be collected on day 0 in order to evaluate in vitro susceptibility of *P. falciparum* isolates to Artemisinin-Lumefantrine. Specimens will be labelled anonymously (patient study number, day of follow-up, date) and stored in liquid nitrogen or -80C freezer. The in vitro drug susceptibility test will be performed in Pasteur Institute of Cambodia. The *P. falciparum* isolates will be cultured in RPMI medium with 5% human serum with serial diluted Artemisinin and Lumefantrine, respectively, under the gas condition of 5% O2, 5% CO2 and 90% N2 in multi-gas incubator. Then, the results will be expressed as IC50, IC90, MIC or percentage (%) of delayed in vitro clearance.

5.3 Safety assessment

Safety will be assessed by recording the nature and incidence of adverse events and serious adverse events. Adverse events will be assessed by direct questioning. An adverse event is defined as any unfavourable, unintended sign, symptom, syndrome or disease that develops or worsens with the use of a medicinal product, regardless of whether it is related to the medicinal product. All adverse events must be recorded on the case report form.

A serious adverse event is defined as any untoward medical occurrence that at any dose:

- results in death, is life threatening;
- requires hospitalization or prolongation of hospitalization;
- results in a persistent or significant disability or incapacity; or
- is a congenital anomaly or birth defect.

'Life-threatening' means that the person was at immediate risk for death; it does not refer to a adverse event that might have caused death if it were more severe. 'Persistent or significant disability or incapacity' means that a person's ability to carry out normal life functions is substantially disrupted.

All serious adverse events occurring during the study must be recorded and reported by the principal investigator to the sponsor, and to WHO (ringwaldp@who.int), regardless of whether the principal investigator considers the events to be related to the investigated medicine.

The investigator will collect information on all people who become pregnant while participating in this study and will record the information on the appropriate form. The person will also be followed to determine the outcome of the pregnancy. Generally, follow-up will be no longer than 6–8 weeks after the estimated delivery date. Any premature termination of pregnancy will be reported. While pregnancy itself is not considered an adverse event or a serious adverse event, any complication of pregnancy or elective termination for medical reasons will be recorded as an adverse event or a serious adverse event. A spontaneous abortion is always considered a serious adverse event and will be reported as such.

6. STUDY ASSESSMENT

6.1 Screening and enrolment

All patients who meet the basic enrolment criteria (age, fever or history of fever if appropriate, symptoms of malaria, absence of danger signs in children in relation to malaria—child unable to drink or breastfeed, vomiting everything, recent history of convulsions, lethargic or unconscious state, unable to sit or stand, difficulty in breathing— absence of signs of severe malaria, absence of severe malnutrition, pregnancy) during screening will be assigned a consecutive number and evaluated in greater depth by clinical staff. In children, care will be taken to detect early signs of febrile diseases other than malaria, as their presence will necessitate exclusion from the evaluation. The most frequent confounding condition is a lower respiratory tract infection: cough or difficult breathing, together with fast breathing, is an indicator for exclusion. Fast breathing is defined as a respiratory frequency > 50/min in infants less than 12 months of age and > 40/min in children aged 12–59 months. Other relatively common febrile conditions are otitis media, tonsillitis, measles and abscesses. Patients with these conditions will not be enrolled but should be treated for both malaria (if they have parasitaemia) and the other infection, as appropriate.

The screening record form (Appendix 5) will be used to record the general information and the clinical observations on each patient being screened. If the patient meets the clinical criteria, he or she will be examined for parasitaemia. Once the patient meets all the enrolment criteria, he or she (if adults are included) or a parent or guardian in case of children will be asked for consent to participate in the study. Children between 12 years and age of majority will also need to provide their assent to participate.

6.2 Follow-up

Patients who meet all the enrolment criteria will be given a personal identification number and will receive treatment only after the study has been fully explained to them and they have willingly provided informed consent. Any person who decides not to participate in the study will be examined, treated and followed-up by the health facility staff according to the standard of care established by the Ministry of Health.

The basic follow-up schedule is summarized in Appendix 6. A case report form (Appendix 7) and a serious adverse event report form (Appendix 8) will be used to record the general information and clinical observations on each patient enrolled into the study. The appointment schedule will be clearly explained, and a follow-up card with a personal identification number will be provided.

The day a patient is enrolled and receives the first dose of medicine is designated 'day 0'. All antimalarial treatment will be given by a study team member under supervision. Enrolled patients will be observed for at least 30 min after treatment to ensure that they do not vomit the medicine. If vomiting occurs within 30 min of treatment, the full treatment dose will be repeated. Ancillary treatment, such as antipyretics, will be provided if necessary, to patients by the study team and documented on the case report form. Patients with persistent vomiting (i.e. necessitating more than a single repeat dose) will be excluded from the study and immediately referred to the health facility staff for appropriate management.

Thereafter, patients are required to undergo regular clinical reassessment. Blood films for parasite counts will be made on days 2, 3 and 7 and then weekly for the remainder of the follow-up period, i.e. on days 14, 21, 28. Patients will be advised to return on any day during the follow-up period if symptoms return and not to wait for the next scheduled visit day. In particular, parents or guardians should be instructed to bring children to the centre at any time if they show any sign of danger (unable to drink or breastfeed, vomiting everything, presenting with convulsions, lethargic or unconscious, unable to sit or stand, presenting with difficult breathing), if they are still sick or if there is any cause for worry. Clinical reassessment will be sufficiently thorough to ensure patient safety and will include assessment not only for potential

treatment failure but also for potential adverse reactions to the medicine. Additionally, blood films will be obtained whenever parasitological reassessment is requested by the clinical staff.

Because many medicines have to be given over several days, the initial visits are critical not only for assessing efficacy but also for ensuring patient safety; defaulters at this stage will not have received a complete course of treatment and may be at risk for clinical deterioration. All reasonable efforts will be made to find defaulters to ensure complete treatment. Similarly, the ultimate success of the study rests on minimizing loss to follow-up. While patients are encouraged to return on their own for scheduled follow-up visits, it is essential that provisions be made ahead of time for locating patients at home if they do not attend as requested. This requires obtaining detailed directions to the home during enrolment, and study team members familiar with the community will be responsible for home visits and means of transport for the patients.

All registered cases will have their address and telephone contact recorded on the form. An appointment timetable from D0 to D28 will be used by the physician to arrange the follow up visits with the patient, either at the health facility or at the patient home according to patient preference. The patient will be informed of the importance of each visit and what procedures will happen during each visit. At least two days before the appointment, the physician will call the case to remind them of the appointment. Patients who visit the physician can meet directly without additional registration in OPD logbook of the health facility. For home visits to patients, the relative forms and blood sample collection-materials will be prepared, and the case will be informed of the procedures before the home visit.

The schedule of treatment and follow-up examinations given in this protocol must be followed to ensure data integrity. Patients who fail to return on days 1 and 2 and miss one dose of the treatment will be withdrawn from the study definitively. After day 3, patients who fail to return on day 7 but are present on day 6 or 8 (likewise days 13/15, days 20/22, days 27/29, may still be included in the analysis. Deviation from the protocol of more than 1 day should, however, be avoided (see also section 3.7).

7. DATA MANAGEMENT

The principal investigator will ensure that the study protocol is strictly adhered to and that all data are collected and recorded correctly on the case report form. Laboratory and clinical data will be recorded on a daily basis on the case report form designed for the study. Data derived from source documents should be consistent with the source documents, or the discrepancies should be explained. Any change or correction to a case report form should be dated and explained and should not obscure the original entry. All case report forms will be checked for completeness.

After the study has been completed, data will be entered into a database by double independent data entry, according to WHO standard procedures.[5] The trial data will be stored in a computer database, maintaining confidentiality.

The principal investigator is responsible for keeping all screening forms, the case report form and the completed subject identification code list in a secure location.

8. STATISTICAL METHODS

8.1 Minimum sample size

As the treatment failure rate to artemether-lumefantrine in the area is 0-6.3% (CMPE 2013), 6.3% has been chosen. At a confidence level of 95% and a precision around the estimate of 5%, a minimum of 450 patients must be included. With a 20% increase to allow loss to follow-up and withdrawals during the 28-day follow-up period, 600 patients (300 Pf and 300 Pv cases, each study site will recruit 100 cases maximum of Pf and 100 cases maximum of Pv**)** should be included in the study per site. Further details on sample size calculations are explained in Appendix 9.

8.2 Analysis of data

The EPI-INFO 6.0 software from USA and Excel sheet program (according to the Informal consultation on monitoring *P. falciparum* and *P. vivax* resistance to antimalarial drugs in the Mekong regions, September 2007 instructions) will be used for data management and analysis. Data will be analysed by two methods: the Kaplan-Meier method and per-protocol analysis. In addition to the reasons for withdrawal listed in section 3.8, patients will be considered withdrawn from the analysis if the PCR results are unclassifiable or if the results of PCR indicate that the failure is due to reinfection with *P. falciparum* or *P. vivax* The final analysis will include:

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[5] WHO/GMP. *Standardized data entry for therapeutic efficacy tests*. Geneva, World Health Organization (http://www.who.int/malaria/resistance).

- a description of all patients screened and the distribution of reasons for non-inclusion in the study;
- a description of all the patients included in the study;
- the proportion of adverse events and serious adverse events in all the patients included in the study;
- the proportion of patients lost to follow-up or withdrawn, with 95% confidence intervals and a list of reasons for withdrawal;
- the cumulative incidence of success and failure rates at day 28, PCR-uncorrected and PCR-corrected; and
- The proportion of early treatment failure, late clinical failure, late parasitological failure and adequate clinical and parasitological response at day 28, with 95% confidence intervals, PCR-uncorrected and PCR-corrected.

Guidelines on calculating the cumulative success or failure rate, the proportion of adequate clinical and parasitological response and treatment failure are given in Appendix 9.

8.3 Dissemination of results

At the end of the study, the principal investigator will submit a report on the study and its main outcome. This report will be shared with the national malaria control programme and the Ministry of Health.

The report will be critically reviewed before publishing by the Scientific Committee of the Institute and will be submitted to the National Malaria Control Programme as well as the sponsor organization. It can be presented during technical meetings with provinces and published in the Bulletin of Control Malaria and other Parasitic Diseases of the Institute. The enrolled patients will be verbally informed about their treatment result and the Health Centre of the study site will received the summary report of the study.

8.4 Amendments to the protocol

After the protocol has been accepted, no change may be made without the agreement of the principal investigator, the sponsor(s) and the institutional review boards.

9. ETHICAL CONSIDERATIONS

9.1 Approval by the national ethical committee

Before the study, official approval to conduct the study will be obtained from Lao National Ethics Committee for Health Research, Government of Lao PDR. (See attached approval).

9.2 Informed consent

Patients will be included in the study only if they or parents or guardians of children give informed consent. The consent request, available in English and translated into Lao, will be read entirely to the patient, parent or guardian. Details about the trial and its benefits and potential risks will be explained. Once any questions have been answered, a signature will be requested on the document (Appendix 10). If the patient or parent or guardian is illiterate, a literate witness must sign; if possible, the signatory will be selected by the participant and will have no connection to the research team. The principal investigator must also obtain the assent of children over the age of 12 years, but their assent should be accompanied by the consent of a parent or guardian. Consent statement for the pregnancy test is also required for female participants of child-bearing age who are sexually active except female aged 12-18 years who are excluded from the study.

9.3 Confidentiality

All information on patients will remain confidential and be shared only by the study team. Unique identifiers will be used for computer-based data entry and blood samples. In all cases, the principal investigator will ensure that screening forms, the case report form and the completed identification code list are kept in locked files.

9.4 Health-care services

Free health care during the duration of the follow-up for illness related to malaria will be provided to the study patients regardless of treatment outcome; this includes any necessary expenses related with hospital admission and to adverse drug reactions, if required.

When prospective or actual subjects are found to have diseases unrelated to malaria, the principal investigator should advise them or parent or guardian to obtain or refer them for medical care.

Any person, who decides not to participate or cannot be enrolled in the study because they do not meet the criteria, will be

referred to the health facility staff. They will be treated with the first line anti-malaria drug according to the national treatment policy and followed-up according to the standard of care established by the Ministry of Health. The antimalarial drug is available at the health centre.

If a patient is withdrawn from the study before the full course of the treatment is completed, the physician must make all necessary arrangements to provide the patient with the full course of the drug currently adapted to be second treatment option known as ASMQ (Artesunate 100mg – Mefloquine 220 mg) with single daily dose over 3 days according to body weight to a total of 3 doses for the treatment of uncomplicated *P. falciparum or P. vivax* malaria also recommended by the national policy (see annex 3).

9.5 Inducement

Subjects shall be reimbursed for their transport to attend all visits to the health centre. Patients will be paid LAK 50,000 for each day in hospital and LAK 50,000 for travelling. No other gifts or payments will be made.

9.6 Community

The village health workers will be informed about the objectives of the study as well as its procedures to ensure that all fever cases will present themselves at the commune health station to have blood examination.

9.7 Clinical trial registration

As required by the WHO, it is necessary to register all therapeutic efficacy studies being done by the country. The clinical trial registration will be done by the Ministry of Health through CMPE on these recommended websites: http://www.ANZCTR.org.au or www.clinicaltrials.gov and http://www.laohrp.com

10. BUDGET TEMPLATE

Budget was estimated by TES site, which may differ on distance, location, supervision and monitoring support needed from provincial and central PI/technical team. Total budget propose is **USD 120,000**

10.1: budget estimation for site 1: Savanakhet province

Human resources			
• professional scientific staff			
• technical staff		3,000	
• local support		2,600	
	Sub-total		**5,600**
Travel and transport			
	Sub-total		**5,000**
Equipment and supplies			
• equipment		0	
• supplies		3,000	
• operational costs (space rental, communication)		0	
	Sub-total		**3,000**
Contingency fees for clinical trials			
• ethical review		0	
• registration		0	
• liability insurance		0	
	Sub-total		**100**
Patient costs		10.000	
	Sub-total		**10,000**
Technical assistance (training, support to research institutions, capacity building)			
	Sub-total		**10,000**
Supervision (national and consultant)			
	Sub-total		**5,000**
Quality assurance system (data validation, slides cross-check)			
	Sub-total		**5,000**
Data management (data entry, data analysis, report writing)			
	Sub-total		**300**
Laboratory support (PCR test)			
	Sub-total		
Miscellaneous			
	Sub-total		**500**
	Grand Total		**44,500**

10.2: Budget estimation for site 2: Salavanh province

Human resources			
• professional scientific staff			
• technical staff		3,000	
• local support		2,500	
	Sub-total		**5,500**
Travel and transport			
	Sub-total		**4,350**
Equipment and supplies			
• equipment		0	
• supplies		2000	
• operational costs (space rental, communication)		0	
	Sub-total		**2,000**
Contingency fees for clinical trials			
• ethical review		0	
• registration		0	
• liability insurance		0	
	Sub-total		**100**
Patient costs		10.000	
	Sub-total		**10,000**
Technical assistance (training, support to research institutions, capacity building)			
	Sub-total		**4,000**
Supervision (national and consultant)			
	Sub-total		**2,200**
Quality assurance system (data validation, slides cross-check)			
	Sub-total		**2,000**
Data management (data entry, data analysis, report writing)			
	Sub-total		**350**
Laboratory support * (PCR test)			
	Sub-total		
Miscellaneous			
	Sub-total		**500**
	Grand Total		**31,000.00**

***** fund from other source

10.3: Budget estimation for site 2: Attopue province

Human resources			
• professional scientific staff			
• technical staff		3,000	
• local support		2,600	
	Sub-total		**5,600**
Travel and transport			
	Sub-total		**4,000**
Equipment and supplies			
• equipment		3,000	
• supplies		000	
• operational costs (space rental, communication)		0	
	Sub-total		**3,000**
Contingency fees for clinical trials			
• ethical review		0	
• registration		0	
• liability insurance		0	
	Sub-total		**100**
Patient costs			
	Sub-total		**10,000**
Technical assistance (training, support to research institutions, capacity building)			
	Sub-total		**10,000**
Supervision (national and consultant)			
	Sub-total		**5,000**
Quality assurance system (data validation, slides cross-check)			
	Sub-total		**5,000**
Data management (data entry, data analysis, report writing)			
	Sub-total		**300**
Laboratory support (PCR test)			
	Sub-total		
Miscellaneous			
	Sub-total		**500**
	Grand Total		**44,500**

11. CURRICULUM VITAE OF THE PRINCIPAL INVESTIGATOR

Family name: CHINDAVONGSA	First name: Keobouphaphone
Place of birth: Vientiane Province	Date of birth: 27th JAN 1968
Current nationality: Lao	

Academic qualifications and dates:

Year	Institution	Degree
2014-2016	Post Graduate Department, Medical Science University, Lao PDR	Master of Science
1990-1996	Faculty of Medical Science, Vientiane Lao PDR	Bachelor of General Medicine
Other training courses:		
2013 (1 month)	Training Management of Malaria Field Operation, Mahidol University, ThaiLand	Certificate
2011 (2 Weeks)	Surveillance of Drug Resistance in GMS, Mahidol University, Thailand	Certificate
March 2008-2009 (one year)	Tropical medicine and Hygiene, Mahidol Uni, Thailand	Diploma
2007 (1 month)	Malaria Prevention and Control, Bureau of Vectorborn Diseases, MOH, Thailand	Certificate
May-August 2001	Programme in Epidemiology and Control of Tropical Diseases, Mahidol Uni, Thailand	Certificate

Appendix 1. DEFINITION OF SEVERE FALCIPARUM MALARIA[6]

Severe manifestation of *P. falciparum* malaria in adults and children

Clinical manifestations

- prostration,
- impaired consciousness,
- respiratory distress (metabolic acidosis),
- multiple convulsions,
- circulatory collapse,
- pulmonary oedema (radiological),
- abnormal bleeding,
- jaundice,
- haemoglobinurea.

Laboratory findings

- severe anaemia (haemoglobin < 5 g/dl, haematocrit < 15%),
- hypoglycaemia (blood glucose < 2.2 mmol/l or 40 mg/dl),
- acidosis (plasma bicarbonate < 15 mmol/l),
- hyperlactataemia (venous lactic acid > 5 mmol/l),
- hyperparasitaemia (> 4% in non-immune patients),
- renal impairment (serum creatinine above normal range for age).

Classification of severe malaria in children

Group 1: children at increased risk for death

- prostration
- respiratory distress

Group 2: children at risk for clinical deterioration

- haemoglobin < 5 g/dl, haematocrit < 15%
- two or more convulsions within 24 h

Group 3: children with persistent vomiting

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[6] World Health Organization. Severe falciparum malaria. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2000, 94(Suppl. 1):1–90.

Appendix 2. MEDICATIONS (WITH ANTIMALARIAL ACTIVITY) THAT SHOULD NOT BE USED DURING THE STUDY PERIOD

- chloroquine, amodiaquine;
- quinine, quinidine;
- mefloquine, halofantrine, lumefantrine;
- artemisinin and its derivatives (artemether, arteether, artesunate, dihydroartemisinin);
- proguanil, chlorproguanil, pyrimethamine;
- sulfadoxine, sulfalene, sulfamethoxazole, dapsone;
- primaquine;
- atovaquone;
- antibiotics: tetracycline*, doxycycline, erythromycin, azythromycin, clindamycin, rifampicin, trimethoprim;
- pentamidine.

* Tetracycline eye ointments can be used.

Appendix 3. DOSING CHART OF ARTEMETHER-LUMEFANTRINE

Tablets containing of artemether 20 mg - lumefantrine 120 mg

Body weight (kg)	Number of tablets		
	Day 0 Twice a day	Day 1 Twice a day	Day 2 Twice a day
5-14	1x2	1x2	1x2
15-24	2x2	2x2	2x2
25-34	3x2	3x2	3x2
35 and above	4x2	4x2	4x2

PRIMAQUINE DOSING

P. falciparum malaria: A single dose of 0.25 mg/kg (body weight) primaquine is given with AL to Pf patients on day 0

P. vivax malaria:

- For G6PD normal patients, a daily dose of 0.25 mg/kg (body weight) primaquine will be given with AL to Pv patients on day 0, and until day 13
- For G6PD deficient patients, weekly dose (0.75 mg/kg bw/week) for 8 weeks will be prescribed after completion of day 28 following up.

For rescue treatment

ARTESUNATE (60 mg)-PYRONARIDINE (180 mg) DOSING:

Artesunate-Pyronaridine (AS-PY), a fixed combination of Artesunate 60mg and Pyronaridine 180 mg in a tablet, will be administered single daily dose over 3 days according to body weight to a total of 3 doses for *P. vivax* and *P. falciparum* cases; The correct drug dosage will be determined from the bellow dosing chart.

Weight (Kg)	**Recommended dose**
20-23	One AS-PY tablet, daily for 3 days
24-44	Two AS-PY tablets, daily for 3 days
45-64	Three AS-PY tablets, daily for 3 days
≥ 65	Four AS-PY, daily for 3 days

APPENDIX 4. Classification of treatment outcomes[7]

Early treatment failure

- danger signs or severe malaria on day 1, 2 or 3 in the presence of parasitaemia;
- parasitaemia on day 2 higher than on day 0, irrespective of axillary temperature;
- parasitaemia on day 3 with axillary temperature ≥ 37.5 ºC;
- parasitaemia on day 3 ≥ 25% of count on day 0.

Late treatment failure

Late clinical failure

- danger signs or severe malaria in the presence of parasitaemia on any day between day 4 and day 28 (day 42) in patients who did not previously meet any of the criteria of early treatment failure;
- presence of parasitaemia on any day between day 4 and day 28 with axillary temperature ≥ 37.5 ºC (or history of fever) in patients who did not previously meet any of the criteria of early treatment failure

Late parasitological failure

- presence of parasitaemia on any day between day 7 and day 28 with axillary temperature < 37.5 ºC in patients who did not previously meet any of the criteria of early treatment failure or late clinical failure

Adequate clinical and parasitological response

- absence of parasitaemia on day 28, irrespective of axillary temperature, in patients who did not previously meet any of the criteria of early treatment failure, late clinical failure or late parasitological failure

[7] WHO. *Susceptibility of* Plasmodium falciparum *to antimalarial drugs. Report on global monitoring 1996–2004*. Geneva, World Health Organization, 2005 (WHO/HTM/MAL/2005.110) (http://www.who.int/malaria/resistance).

Appendix 5. CASE SCREENING FORM

Case screening form	
Health centre name: Locality: District: Province:	Study number: Patient screening number: Date of visit (dd-mmm-yyyy):
Demographic data	
Date of birth (dd-mmm-yyyy): or estimated age: in: ☐ months or ☐ years Height (cm): Weight (kg): Sex: ☐ Male ☐ Female If female, is the patient pregnant? ☐ Yes ☐ No ☐ Not sure If pregnant, provide the date of the last menstrual period (dd-mmm-yyyy):	
Pre-treatment temperature	
History of fever in previous 24 h? ☐ Yes ☐ No Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral	
Thick and thin blood smears for estimation of *P. falciparum/ P. vivax* parasite counts	
Species: ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae* Were species other than *P. falciparum/ P.vivax* present? ☐ Yes ☐ No **(If yes, patient is not eligible).** Approximate number of *P. falciparum/ P.vivax* asexual parasites: Presence of 1–100 parasites / 3–6 white blood cells? ☐ Yes ☐ No **(If no, patient is not eligible)** Presence of *P. falciparum/ P.vivax* gametocytes? ☐ Yes ☐ No	
Has a blood sample for PCR been collected? ☐ Yes ☐ No	
Haemoglobin: g/dl Haematocrit: %	
Urinary analysis (pregnancy test for female patients)	
Result of pregnancy test: ☐ Positive ☐ Negative **(If positive, patient is not eligible)**	
Inclusion criteria	
• age between 6 months and above • mono-infection with *P. falciparum* or *P.vivax* confirmed by positive blood smear (i.e. no mixed infection) • *P. falciparum* parasitaemia between 250 and 100,000/µl of asexual forms; • *P. vivax* parasitaemia between 250 and 60,000/µl of asexual forms • measured temperature (depending on method of measurement) or history of fever within previous 24 h • ability to swallow oral medication • ability and willingness to comply with the study protocol for the duration of the study and to comply with the study visit schedule • absence of severe malnutrition (defined as per protocol)	
Does the patient meet all the inclusion criteria? ☐ Yes ☐ No **(If no, patient is not eligible)**	

Case screening form (page 2)	
Exclusion criteria	
• signs and symptoms of severe or complicated malaria requiring parenteral treatment according to WHO criteria (Appendix 1) • mixed or mono-infection with another *Plasmodium* species (*or P.vivax)* detected by microscopy • severe malnutrition • febrile conditions caused by diseases other than malaria or other known underlying chronic or severe diseases • regular medication which interferes with antimalarial pharmacokinetics • history of hypersensitivity reactions or contraindications to the medicine tested • positive pregnancy test or breastfeeding • Unable to or unwilling to take contraceptives.	
Does the patient meet any of the exclusion criteria? ☐ Yes ☐ No **(If yes, the patient is not eligible)**	
If yes, please specify the reason for exclusion:	
Patient informed consent and assent	
Consent form signed: ☐ Yes ☐ No Assent form signed: ☐ Yes ☐ No	Patient identity number: Date (dd-mmm-yyyy):

Appendix 6. SCHEDULE OF FOLLOW-UP ACTIVITIES

	0	1	2	3	7	14	21	28	Any other
Procedure									
Clinical assessment	X	X	X	X	X	X	X	X	(X)
Temperature	X	X	X	X	X	X	X	X	(X)
Blood slide for parasite count	X	X	X	X	X	X	X	X	(X)
Urine sample	(X)								
Blood for:									
genotyping	X				(X)	(X)	(X)	(X)	(X)
haemoglobin or haematocrit	(X)					(X)		(X)	(X)
molecular markers	(X)				(X)	(X)	(X)	(X)	(X)
antimalarial blood concentration	(X)				(X)	(X)	(X)	(X)	(X)
Treatment									
Medicine to be tested	X	X	X						
Rescue treatment		(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)

Parentheses denote conditional or optional activities. For example, treatment would be given on days 1 and 2 only for 3-day dosing. On day 1, the patient should be examined for parasitaemia if he or she has any danger signs. Rescue treatment could be given on any day, provided that the patient meets the criteria for treatment failure. Extra days are any days other than regularly scheduled follow-up days when the patient returns to the facility because of recurrence of symptoms. On extra days, blood slides may be taken routinely or at the request of the clinical staff.

Day 0

Screening

- clinical assessment, including measurement of weight and height; referral in cases of severe malaria or danger signs;
- measurement of temperature;
- parasitological assessment;
- pregnancy test (if necessary);
- Informed consent.

Enrolment

- treatment, first dose;
- blood sampling for genotyping.

Optional

- urinary test to detect antimalarial drugs;
- haemoglobin/haematocrit;
- molecular markers of drug resistance;
- in vitro test;
- antimalarial drug blood concentration.

Day 1

- clinical assessment; referral in cases of severe malaria or danger signs;
- measurement of axillary temperature;
- parasitological assessment in cases of severe malaria or danger signs;
- treatment, second dose or alternative treatment in case of early treatment failure.

Day 2

- clinical assessment; referral in cases of severe malaria or danger signs;
- measurement of axillary temperature;
- parasitological assessment;
- treatment, third dose or alternative treatment in case of early treatment failure.

Day 3, day 7, day 14, day 21, day 28, any other day

- clinical assessment; referral in cases of severe malaria or danger signs;
- measurement of axillary temperature;
- parasitological assessment;
- alternative treatment in cases of treatment failure;
- pregnancy test at the end of follow-up (if necessary);
- blood sampling for genotyping to distinguish between recrudescence and reinfection in cases of treatment failure after day 7.

Optional (after day 7)

- haemoglobin/haematocrit;
- blood sampling for molecular markers for drug resistance, antimalarial blood concentration.

Appendix 7. CASE REPORT FORMS

Case report form: follow-up day 0

Health centre name:	Study number:
Locality:	Patient identity number:
District:	Date of visit (dd-mmm-yyyy):
Province:	

Demographic data

Date of birth (dd-mmm-yyyy): or estimated age: in: ☐ months or ☐ years

Height (cm): Weight (kg): Sex: ☐ Male ☐ Female

If female, is the patient pregnant? ☐ Yes ☐ No ☐ Not sure **(If yes, patient is not eligible).**

If pregnant, provide the date of the last menstrual period (dd-mmm-yyyy):

Pre-treatment temperature

History of fever in previous 24 h? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for *P. falciparum/P.vivax*: quantitative parasite counts and qualitative gametocyte counts

Average number of asexual *P. falciparum/ P.vivax* parasites/µl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No **(If yes, patient is not eligible).**

If yes, which species? ☐ *P. falciparum,* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Has blood sample for PCR been collected? ☐ Yes ☐ No

Urinary test for antimalarial drugs

Test used: Test result: ☐ Positive ☐ Negative

Test used: Test result: ☐ Positive ☐ Negative

Prior medication

All prior medication, including natural remedies and homeopathic medicines, taken within the previous 14 days should be reported in this section.
Has the patient taken any prior antimalarial medication? ☐ Yes ☐ No. If yes, please specify below. Either the date of stopping or the 'ongoing' box should be checked.

Medicine name (generic name)	Dates	Ongoing (Yes = ☒)	Total daily dose and unit (e.g. 400 mg)	Route of administration	Indication for use
	Start: Stop:	☐			
	Start: Stop:	☐			
	Start: Stop:	☐			

Case report form: follow-up day 0 (page 2)				
Medication administration				
Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: follow-up day 1

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

If yes, perform thick blood smear.

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/µl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: follow-up day 2

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/µl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: follow-up day 3

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum*/*P.vivax* parasite counts

Average number of asexual *P. falciparum/p.vivax* parasites/µl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: follow-up day 7

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

History of fever within previous 24 h? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/μl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Has a blood sample for PCR been collected? ☐ Yes ☐ No

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: follow-up day 14

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

History of fever within previous 24 h? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/μl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Has a blood sample for PCR been collected? ☐ Yes ☐ No

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: follow-up day 21

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

History of fever within previous 24 h? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/μl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Has a blood sample for PCR been collected? ☐ Yes ☐ No

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: day ___(any other day that is not part of regular follow-up)

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

History of fever within previous 24 h? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/μl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Has a blood sample for PCR been collected? ☐ Yes ☐ No

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Case report form: final day of follow-up 28

Study number:

Patient identity number:

Date of visit (dd-mmm-yyyy):

Clinical status

Presence of danger signs or signs of severe or complicated malaria? ☐ Yes ☐ No

History of fever within previous 24 h? ☐ Yes ☐ No

Temperature: ºC ☐ Axillary ☐ Tympanic ☐ Rectal ☐ Oral

Thick blood smears for estimation of *P. falciparum/P.vivax* parasite counts

Average number of asexual *P. falciparum/P.vivax* parasites/μl:

Presence of *P. falciparum/P.vivax* gametocytes? ☐ Yes ☐ No

Were species other than *P. falciparum/P.vivax* present? ☐ Yes ☐ No

If yes, which species? ☐ *P. falciparum* ☐ *P. vivax* ☐ *P. ovale* ☐ *P. malariae*

Has a blood sample for PCR been collected? ☐ Yes ☐ No

Adverse events

Presence of an adverse event? ☐ Yes ☐ No

If yes, name the adverse event:

Is it a serious adverse event? ☐ Yes ☐ No. If yes, inform the sponsor.

Medication administration

Name(s) of antimalarial drug(s)	Time of dose (hh:min)	Number of tablets	Did the patient vomit?	Time of vomiting (hh:min)
			☐ Yes ☐ No	
			☐ Yes ☐ No	
Name(s) of other medicine(s)				
			☐ Yes ☐ No	
			☐ Yes ☐ No	

Urinary analysis (pregnancy test for female patients)

Patients with a positive pregnancy test must be followed up for 6–8 weeks after delivery

Result of pregnancy test: ☐ Positive ☐ Negative Date of test (dd-mmm-yyyy):

If the patient is pregnant, follow-up of the pregnancy is required, including: clinical examination of the infant at birth and 6-8 weeks after birth. Please provide comments below. If needed fill in the serious adverse event report form):

Case report form: final day of follow-up 28 (page 2)

Overall assessment

Outcome:

- ☐ adequate clinical and parasitological response
- ☐ early treatment failure
- ☐ late clinical failure
- ☐ late parasitological failure
- ☐ lost to follow-up
- ☐ withdrawn

Outcome occurred on follow-up day: (e.g. 1, 2, 3, 7, 14, …)

PCR:

- ☐ *P. falciparum* recrudescence/*P.vivax* replapsing
- ☐ *P. Falciparum/P.vivax* reinfection
- ☐ other species
- ☐ mixed with *P. falciparum/vivax* recrudescence/relapsing
- ☐ mixed with *P. falciparum/P.vivax* reinfection
- ☐ unknown

PCR corrected results:

- ☐ adequate clinical and parasitological response
- ☐ early treatment failure
- ☐ late clinical failure
- ☐ late parasitological failure
- ☐ lost to follow-up
- ☐ withdrawn

Reason for withdrawal:

Other comments:

Appendix 8. SERIOUS ADVERSE EVENT REPORT FORM

Serious adverse event report form	
Health centre name: Locality: District: Province:	Study number: Patient identity number: Date of visit (dd-mmm-yyyy): Follow-up day:
Demographic data	
Date of birth (dd-mmm-yyyy): or estimated age: in: ☐ months or ☐ years Height (cm): Weight (kg): Sex: ☐ Male ☐ Female If female, is the patient pregnant? ☐ Yes ☐ No ☐ Not sure If pregnant, provide the date of the last menstrual period (dd-mmm-yyyy):	
Serious adverse event	
Type of event: ☐ Death ☐ Life-threatening ☐ Hospitalization or prolongation of hospitalization ☐ Permanent disability ☐ Congenital anomaly or birth defect Date of occurrence (dd-mmm-yyyy):	
Describe the serious adverse event (include all relevant laboratory results):	
Describe how the reaction was treated:	

Serious adverse event report form (page 2)

Comments (e.g. relevant medical history, drug allergies, previous exposure to similar drugs, other laboratory data, whether reaction abated after stopping the drug, whether reaction reappeared after reintroduction):

Outcome

☐ Recovered completely

☐ Not yet recovered

☐ Recovered with long-term consequences

If patient recovered, provide date of recovery (dd-mmm-yyyy):

Medicines (list the **medicine suspected of causing** the serious adverse event as well as all **concomitant medicines**)

Brand name, batch number, manufacturer name (list suspected medicine first)	Daily dose	Route	Start date	End date	Indications for use

Reporting officer

Name:

Qualification:

Address:

Phone:

Fax:

Email:

Signature: Date:

Appendix 9. GUIDELINES FOR ANALYSIS OF RESULTS

End-point for day X (X = 28 or 42)	PCR-uncorrected results	
	Cumulative success or failure rate (Kaplan-Meier analysis)	Proportion (per-protocol analysis)
Adequate clinical and parasitological response on day X	Success	Success
Early treatment failure	Failure	Failure
Late clinical failure before day 7	Failure	Failure
Late clinical failure or late parasitological failure on or after day 7	Failure	Failure
Other species infection	Censored day of infection	Excluded from analysis
Lost to follow-up	Censored last day of follow-up according to timetable	Excluded from analysis
Withdrawal and protocol violation	Censored last day of follow-up according to timetable before withdrawal or protocol violation	Excluded from analysis

End-point for day X (X = 28 or 42)	PCR-corrected results	
	Cumulative success or failure rate (Kaplan-Meier analysis)	Proportion (per-protocol analysis)
Adequate clinical and parasitological response at day X	Success	Success
Early treatment failure	Failure	Failure
Late clinical failure before day 7	Failure	Failure
Late clinical failure or late parasitological failure on or after day 7		
• falciparum recrudescence*	Failure	Failure
• falciparum reinfection*	Censored day of reinfection	Excluded from analysis
• other species mixed with falciparum recrudescence	Failure	Failure
• other species mixed with falciparum reinfection	Censored day of reinfection	Excluded from analysis
• other species infection	Censored day of infection	Excluded from analysis
• undetermined or missing PCR	Excluded from analysis	Excluded from analysis
Lost to follow-up	Censored last day of follow-up according to timetable	Excluded from analysis
Withdrawal and protocol violation	Censored last day of follow-up according to timetable before protocol violation or withdrawal	Excluded from analysis

* WHO. *Methods and techniques for clinical trials on antimalarial drug efficacy: genotyping to identify parasite populations*. Geneva, World Health Organization, 2008 (http://www.who.int/malaria/resistance).

Appendix 10. CONSENT AND ASSENT FORMS[8]

Informed consent form for adults

This informed consent form is for adults over 18 years of age who attend…… (indicate name of sentinel site clinic), who have been invited to participate in a study to evaluate the efficacy of artemether-lumefantrine for the treatment of uncomplicated P. *falciparum and P. vivax* malaria.

Name of principal investigator:	Dr. Keobouphaphone Chindavongsa
Name of organization:	Center of Malariology, Parasitology and Entomology
Name of sponsor:	Ministry of Health
Name of proposal and version:	Lao 1/2022

This informed consent form has two parts:

I. Information sheet (to share information about the study with you)

II. Certificate of consent (for signatures if you agree to take part)

You will be given a copy of the full informed consent form.

Part I. Information sheet

My name is Dr. keobouphaphone Chindavongsa and I work for the Ministry of Health. We are doing a study on the treatment of malaria. Malaria is a dangerous disease; however, it can be treated with medicine. The purpose of this study is to confirm that the medicine, called artemether-lumefantrine, is still effective for curing malaria.

We are inviting all adults and children aged 6 months to 60 years living in this area to take part in this study.

I am going to give you information and invite you to participate in this surveillance study. Before you decide whether to participate, you can talk to anyone you feel comfortable with. There may be some words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, you can ask me, the study doctor or the staff.

Your participation in this study is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this project, we will offer the treatment that is routinely provided in this clinic for malaria, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

You will receive 3 doses of medicine over 3 days. The medicine, artemether-lumefantrine, is recommended by the Ministry of Health. The Ministry regularly conducts studies to make sure the medicine is still working. The medicine is made by Novartis; it is produced with the trade name: Coartem®. You should know that like other antimalarial medicines, it may cause some side-effects such as: Nausea, stomach cramps and dizziness. These effects are usually minor and resolve quickly.

If we find that the medicine is not working, we will use what is called 'rescue medicine'. This medicine is called quinine-doxycycline and is given over 7 days base National guideline treatment. You should know that this medicine has some minor side-effects: diarrhea, dizziness, headache, nausea, nervousness, restlessness, stomach cramps, and vomiting. These side effects are usually minor and resolve quickly.

The study will take place over 28 days. During that time, you will have to come to the health facility for 1 hour each day for the first 3 days and then every week for 4 weeks (8 visit days) according to the scheduled dates given to you. At the end of 4 weeks, the study will be finished. At each visit, you will be examined by a physician.

Today, we will take blood for testing and you will receive the first dose of treatment.

[8] http://www.who.int/rpc/research_ethics/en/

On the

- 2nd visit: you will receive the 2nd dose of treatment.
- 3rd visit: you will receive the 3rd dose of treatment plus a blood test.
- 4th, 5th, 6th, 7th, 8th visits, you will have a blood test.

For the blood test, around 5 drops and 5 ml, will be taken from your fingertip and venous respectively. You may experience a bit of pain or fear when your finger is pricked and your venous punctured. The pain should disappear within 1 day. The first blood sample from your finger will be dropped onto a slide and a small piece of paper. The blood samples will only be used to study the malaria in your blood. The second blood sample will be drained in laboratory tube for evaluation in vitro susceptibility of *P. falciparum* isolates to Artemisinin-Lumefantrine. Upon testing results indicated as *P. vivax* infection, additional blood test to evaluate glucose-6-phosphate dehydrogenase (G6PD) status will be performed. If result indicated of G6PD deficiency, you will receive weekly dose treatment by using PQ for 8 weeks course. The examination of some of the blood samples will only be done after the study and it will not affect the success of the treatment. Nothing else will be done with your blood. The blood samples will be destroyed after the study when no more verification of the information collected is needed.

If you do not attend the scheduled visit, the health staffs will visit you at home.

As already mentioned, this medicine can have some unwanted or unexpected effects; however, we will follow you closely and keep track of these effects, if they arise, and of any other problems. We will give you a telephone number to call if you notice anything out of the ordinary or if you have concerns or questions. You can also come to this health facility at any time and ask to see staff at malaria clinic. If you experience side-effects, we may use some other medicine, free of charge, which will help to reduce the symptoms or reactions, or we may stop one or more of the medicines. If this is necessary we will discuss it together. You will always be consulted before we move to the next step.

Your participation will help us to make sure the medicine is still working, and this will benefit society and future generations. If you decide to participate in this study, any illnesses related to malaria or to the malaria treatment will be treated at no charge to you. We will give you 50,000 Kip to pay for your travel expenses to the clinic.

We will not share the identity of participants in the study with anyone. The information that we collect from this study will be kept confidential. Any information collected about you will have a number on it instead of your name. Only the study team members will know what your number is, and we will lock that information up.

We will share the knowledge that we get from this study with you before it is made available to the public. Confidential information will not be shared. There will be small meetings in the community, and these will be announced. Afterwards, we will publish the results and make them available so that other interested people may learn from our study.

This proposal has been reviewed and approved by the Lao National Ethic Committee for Health Research, Government of Lao PDR This is a committee that makes sure that study participants are protected from harm.

Part II. Certificate of consent

I have been invited to participate in a study of a medicine used to treat malaria.

I have read the above information, or it has been read to me. I have had the opportunity to ask questions, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Print name of participant: _____

Signature of participant: _____

Date: _____
(dd/mmm/yyyy)

Witness' signature: (A witness' signature and the patient's thumbprint are required only if the patient is illiterate. In this case, a literate witness must sign. If possible, this person should be selected by the participant and should have no connection with the study team.)

I have witnessed the accurate reading of the consent form to the potential participant, who has had the opportunity to ask questions. I confirm that the participant has given consent freely.

Print name of witness: _____ and thumbprint of participant:

Signature of witness: _____

Date: _____
(dd/mmm/yyyy)

Investigator's signature:

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, who has had the opportunity to ask questions. I confirm that the participant has given consent freely.

Print name of investigator: _____

Signature of investigator: _____

Date: _____
(dd/mmm/yyyy)

A copy of this informed consent form has been provided to the participant. _____ (initials of the principal investigator or assistant).

Informed consent form for parents or guardian of prospective children or minor participants

This informed consent form is for parents or guardians of children aged 6 months and above who attend…… …….. (name of the sentinel site clinic), who have been invited to participate in a study to evaluate the efficacy of artemether-lumefantrine for the treatment of uncomplicated *P. falciparum* and *P. vivax* malaria.

Name of principal investigator:	Dr. keobouphaphone Chindavongsa
Name of organization:	Center of Malariology, Parasitology and Entomology
Name of sponsor:	Ministry of Health
Name of proposal and version:	Lao 1/2021

This informed consent form has two parts:

I. Information sheet (to share information about the study with you)

II. Certificate of consent (for signatures if you agree to take part)

You will be given a copy of the full informed consent form.

Part I: Information sheet

My name is Dr. keobouphaphone Chindavongsa, and I work for the Ministry of Health. We are doing a study on the treatment of malaria. Malaria is a dangerous disease; however, it can be treated with medicine. The purpose of this study is to confirm that the medicine, called artemether-lumefantrine, is still effective for curing malaria.

We are inviting all adults and children aged 6 months to 18 years old living in this area to take part in this study.

I am going to give you information and invite you to consent to have your child participate in this study. Before you decide whether you want your child to participate, you can talk to anyone you feel comfortable with. There may be some words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, you can ask me, the study doctor or the staff. . For children aged from 12 years to age of majority specify that the child will need to provide assent to participate and in case of disagreement his/her choice will prevail.

Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services your child receives at this clinic will continue and nothing will change. If you choose your child should not participate in this project, we will offer the treatment that is routinely provided in this clinic for malaria, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Your child will receive 3 doses of medicine over 3 days. The medicine, artemether-lumefantrine, is recommended by the Ministry of Health. As the parasites that cause malaria can become resistant to the medicine, the Ministry regularly does studies to make sure the medicine is still working. The medicine is made by Novartis Pharmaceuticals Istanbul, Turkey with the brand name Coartem®. This medicine is known to be very effective, but you should know that it has some minor side-effects. You should know that like other antimalarial medicines, it may cause some side-effects such as: Nausea, stomach cramps and dizziness. These effects are usually minor and resolve quickly.

If we find that the medicine is not working, we will use what is called ‘rescue medicine’. The medicine is called quinine-doxycycline combination and is given over 7 days base national guideline treatment. You should know that this medicine has some minor side-effects: diarrhea, dizziness, headache, nausea, nervousness, restlessness, stomach cramps and vomiting. These effects are usually minor and resolve quickly.

The study will take place over 28 days. During that time, your child will have to come to the health facility for 1 hour each day for 9 days according to the scheduled dates given to you. At the end of 4 weeks, the study will be finished. At each visit, your child will be examined by a physician. You may stay with your child during each of the visits and during the procedures.

Today, we will take blood for testing and your child will receive the first dose of treatment.

On the

- 2nd visit, your child will receive the 2nd dose of treatment.
- 3rd visit, your child will receive the 3rd dose of treatment plus a blood test.
- 4th, 5th, 6th, 7th, 8th, visits, your child will have a blood test.

For the blood test, around 5 drops and 5 ml, will be taken from your fingertip and venous respectively. You may experience a bit of pain or fear when your finger is pricked and your venous punctured. The pain should disappear within 1 day. The first blood sample from your finger will be dropped onto a slide and a small piece of paper. The blood samples will only be used to study the malaria in your blood. The second blood sample will be drained in laboratory tube for evaluation in vitro susceptibility of *P. falciparum* isolates to Artemisinin-Lumefantrine. Upon testing results indicated as *P. vivax* infection, additional blood test to evaluate glucose-6-phosphate dehydrogenase (G6PD) status will be performed. If result indicated of G6PD deficiency, you will receive weekly dose treatment by using PQ for 8 weeks course. The examination of some of the blood samples will only be done after the study and it will not affect the success of the treatment. Nothing else will be done with your blood. The blood samples will be destroyed after the study when no more verification of the information collected is needed.

If you do not attend the scheduled visit, the health staffs will visit your child at home.

The medicine can have some unwanted or unexpected effects; however, we will follow your child closely and keep track of these effects, if they arise, and of any other problems. We will give you a telephone number to call if you notice anything out of the ordinary or if you have concerns or questions. You can also bring your child to this health facility at any time and ask to see staff at malaria clinic. If your child experiences side-effects, we may use some other medicine, free of charge, which will help to reduce the symptoms or reactions, or we may stop one or more of the medicines. If this is necessary, we will discuss it together. You will always be consulted before we move to the next step.

Your child's participation will help us to make sure the medicine is still working, and this will benefit society and future generations. If you decide that your child will participate in this study, any illnesses related to malaria or to the malaria treatment will be treated at no charge to you. We will give you the equivalent of LAK 50,000 to pay for your travel expenses to the clinic.

We will not share the identity of participants in the study with anyone. The information that we collect from this study will be kept confidential. Any information collected about your child will have a number on it instead of your child's name. Only the study team members will know what the number is, and we will lock that information up.

We will share the knowledge that we get from this study with you before it is made available to the public. Confidential information will not be shared. There will be small meetings in the community, and these will be announced. Afterwards, we will publish the results and make them available so that other interested people may learn from our study.

This proposal has been reviewed and approved by Lao National Ethic Committee for Health Research, Government of Lao PDR. This is a committee that makes sure that study participants are protected from harm.

Part II: Certificate of consent

I have been invited to have my child participate in a study of a medicine used to treat malaria.

I have read the above information, or it has been read to me. I have had the opportunity to ask questions, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to my child's participation in this study.

Print name of participant: _____

Print name of parent or guardian: _____

Signature of parent or guardian: _____

Date: _____
(dd/mmm/yyyy)

Witness' signature: (A witness' signature and the thumbprint of the participant's parent or guardian are required only if the parent or guardian is illiterate. In this case, a literate witness must sign. If possible, this person should be selected by the participant's parent or guardian and should have no connection with the study team.)

I have witnessed the accurate reading of the consent form to the potential participant's parent or guardian, who has had the opportunity to ask questions. I confirm that the participant's parent or guardian has given consent freely.

Print name of witness: _____ and thumbprint of parent/guardian:

Signature of witness: _____

Date: _____

(dd/mmm/yyyy)

Investigator's signature:

I have accurately read or witnessed the accurate reading of the consent form to the potential participant's parent or guardian, who has had the opportunity to ask questions. I confirm that the participant's parent or guardian has given consent freely.

Print name of investigator: _____

Signature of investigator: _____

Date: _____

(dd/mmm/yyyy)

A copy of this informed consent form has been provided to participant's parent or guardian. _____ (initials of the principal investigator/assistant).

An informed assent form will _____ or will not _____ be completed.

Informed assent form

This informed assent form is for children aged 12–18 years old who attend……..(indicate name of the sentinel site clinic) and who have been invited to participate in a study designed to evaluate the efficacy of artemether-lumefantrine for the treatment of uncomplicated *P. falciparum* and *P. vivax* malaria.

Name of principal investigator:	Dr. keobouphaphone Chindavongsa
Name of organization:	Center of Malariology, Parasitology and Entomology
Name of sponsor:	Ministry of Health
Name of proposal and version:	Lao 1/2021

This informed assent form has two parts:

I. Information sheet (to share information about the study with you)

II. Certificate of assent (for signatures if you agree to take part)

You will be given a copy of the full informed assent form.

Part I. Information sheet

My name is Dr. keobouphaphone Chindavongsa, and I work for the Ministry of Health. We are doing a study on the treatment of malaria. Malaria is a dangerous disease; however, it can be treated with medicine. The purpose of this study is to confirm that the medicine, called artemether-lumefantrine, is still effective for curing malaria.

We are inviting adult children aged 12-18 years living in this area to take part in this study.

I am going to give you information and invite you to participate in this study. You can choose whether you want to participate. We have discussed this study with your parent(s) or guardian, and they know that we are also asking you for your agreement. If you decide to participate in the study, your parent(s) or guardian also has to agree. If you do not wish to take part in the study, you do not have to, even if your parents have agreed. It is your choice. If you decide not to participate, nothing will change; this is still your clinic. Even if you say 'Yes' now, you can change your mind later and it will still be okay. You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. There may be some words you do not understand or things that you want me to explain more because you are interested or concerned. Please ask me to stop at any time, and I will take time to explain.

Interviewer: I have checked with the child, and he or she understands that participation is voluntary. _____ (initials)

You will receive 3 doses of medicine over 3days. The medicine, artemether-lumefantrine, is recommended by the Ministry of Health. The Ministry regularly conducts studies to make sure the medicine is still working. The medicine is made by Novartis Pharmaceuticals Istanbul, Turkey for Novartis Pharma AG, Basle, Switzerland under License from the PRC. This medicine is known to be very effective, but you should know that it has some minor side-effects: i.e. dizziness, nausea, vomiting and diarrhea.

The study will take place over 28 days. During that time, you will have to come to the health facility for 1 hour each day for 9 days. At the end of 4 weeks, the study will be finished.

For the blood test, around 5 drops and 5 ml, will be taken from your fingertip and venous respectively. You may experience a bit of pain or fear when your finger is pricked and your venous punctured. The pain should disappear within 1 day. The first blood sample from your finger will be dropped onto a slide and a small piece of paper. The blood samples will only be used to study the malaria in your blood. The second blood sample will be drained in laboratory tube for evaluation in vitro susceptibility of *P. falciparum* isolates to Artemisinin-Lumefantrine. Upon testing results indicated as *P. vivax* infection, additional blood test to evaluate glucose-6-phosphate dehydrogenase (G6PD) status will be performed. If result indicated of G6PD deficiency, you will receive weekly dose treatment by using PQ for 8 weeks course. The examination of some of the blood samples will only be done after the study and it will not affect the success of the treatment. Nothing else will be done with your blood. The blood samples will be destroyed after the study when no more verification of the information collected is needed.

Interviewer: I have checked with the child, and he or she understands the procedures. _____ (initials)

The medicine can have some unwanted effects or some effects that we are not currently aware of; however, we will follow you closely and keep track of any unwanted effects, if they arise, or any other problems. If anything unusual happens to you, we need to know, and you should feel free to call us any time with your concerns or questions. If you get sick or have concerns or questions between scheduled visits to clinic, you should let me or the staff nurse know. You do not have to wait for a scheduled visit. We have also given your parents information about what to do if you are hurt or get sick during the study.

Interviewer: I have checked with the child, and he or she understands the risks and discomforts. _____ (initials)

Your participation will help us to make sure the medicine is still working, and this will benefit society and future generations. If you decide to participate in this study, any illnesses related to malaria or to the malaria treatment will be treated at no charge to you.

Because you live quite far from the clinic, we will give your parents or guardian enough money to pay for the trip here and back and a bednet.

Interviewer: I have checked with the child, and he or she understands the benefits. _____ (initials)

We will not tell other people that you are participating in this study, and we will not share information about you with anyone who does not work in the study. Information about you that will be collected from the study will be put away, and no one but the study team will be able to see it. Any information about you will have a number on it instead of your name. Only the study team will know what your number is, and we will lock that information up.

When we have finished the research, I will sit down with you and your parent or guardian and tell you about what we learnt. Afterwards, we will be telling more people, scientists and others, about the study and what we found. We will do this by writing and sharing reports and data and by going to meetings with people who are interested in the work we do.

You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby; you can come and see us. If you want to talk to someone else whom you know, like your teacher, doctor or auntie, that is okay too.

Part II: Certificate of assent

I have been invited to participate in a study of the efficacy of an antimalarial medicine. I have read this information (or had the information read to me), and I understand it. I have had my questions answered and know that I can ask questions later if I have them. I agree to take part in the study. _____ (initials) or I do not wish to take part in the study and I have not signed the assent below. _____ (initials)

Child's signature (only if the child assents):

Print name of child: _____

Signature of child: _____

Date (dd/mmm/yyyy): _____

Witness' signature: (A witness' signature and the child's thumbprint are required only if the child is illiterate. In this case, a literate witness must sign. If possible, this person should be selected by the participant and should have no connection with the study team.)

I have witnessed the accurate reading of the assent form to the potential participant, who has had the opportunity to ask questions. I confirm that the participant has given consent freely.

Print name of witness: _____

Signature of witness: _____

Date (dd/mmm/yyyy): _____

and thumbprint of the child or minor:

Investigator's signature:

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, who has had the opportunity to ask questions. I confirm that the participant has given consent freely.

Print name of investigator: _____

Signature of investigator: _____

Date (dd/mmm/yyyy): _____

A copy of this informed assent form has been provided to the participant. _____ (initials of the principal investigator or assistant).

Consent statement for a pregnancy test

I have been invited to participate in a study on the medicine used to treat malaria. I have been asked to supply a specimen of urine at the first visit and at day 28 or on the day of withdrawal from the study, all of which will be used for pregnancy testing. I understand that the results of the tests will be kept fully confidential and anonymous. I understand that I must avoid becoming pregnant during the study because the medicine I will be taking would be dangerous for my child. I have discussed the different methods of birth control with medical staff at health center in the area and I have been offered a barrier contraceptive. I understand that if the test is positive, I will not be eligible to participate in this study.

Participant's signature:

I accept to be tested. _____ (participant's initials) or

I do not want to be tested, and I have not signed the consent form below. _____ (participant's initials)

Print name of participant: _____

Signature of participant: _____

Date: _____
(dd/mmm/yyyy)

Witness' signature: (A witness' signature and the thumbprint of the participant are required only if the participant is illiterate. In this case, a literate witness must sign. If possible, this person should be selected by the participant and should have no connection with the study team.)

I have witnessed the accurate reading of the consent form to the potential participant, who has had the opportunity to ask questions. I confirm that the participant has given consent freely.

Print name of witness: _____ and thumbprint of the participant:

Signature of witness: _____ 

Date: _____
(dd/mmm/yyyy)

Investigator's signature:

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, who has had the opportunity to ask questions. I confirm that the participant has given consent freely.

Print name of investigator: _____

Signature of investigator: _____

Date: _____
(dd/mmm/yyyy)

A copy of this consent statement has been provided to participant. _____ (initials of the principal investigator or assistant).

Consent form in local language:

ເອກກະສານແນບທ້າຍ: ໃບຍິນຍອມ[9]

ຕົວຢ່າງໃບຍິນຍອມສຳຫຼັບອາສາສະມັກທີ່ເປັນຜູ້ໃຫຍ່

ແບບໃບຍິນຍອມນີ້ໃຊ້ສຳຫຼັບອາສາສະມັກຜູ້ໃຫຍ່ 18 ປີ ຂຶ້ນໄປ ຜູ້ທີ່ມາໃຊ້ບໍລິການຢູ່ສະຖານບໍລິການ ..... (ຊື່ສະຖານບໍລິການ) ແລະ ໄດ້ຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມ ການສຶກສາວິໄຈປະສິດທິພາບຂອງຢາ ອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ສຳຫຼັບປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍຊະນິດຟານຊີປາລອມ ຫຼື ວີວັກ.

ຊື່ຫົວໜ້າທີມວິໄຈ:	ດຣ. ແກ້ວບຸຜາພອນ ຈິນດາວົງສາ
ຊື່ສະຖານທີ່ເຮັດວຽກ:	ສູນໄຂ້ຍຸງ, ແມ່ກາຝາກ ແລະ ແມງໄມ້
ຊື່ອົງການສະໜັບສະໜູນ:	ກະຊວງສາທາລະນະສຸກ
ຊື່ບົດສະເໜີໂຄງການ:	Lao 1/2022

ແບບຍິນຍອມໃຫ້ເຮັດການສຶກສາວິໄຈນີ້ປະກອບດ້ວຍ 2 ສ່ວນ:

1. **ຂໍ້ມູນ**ກ່ຽວກັບການສຶກສາວິໄຈ
2. ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການສຳລັບອາສາສະໝັກທີ່ຍິນດີເຂົ້າຮ່ວມ

ອາສາສະມັກຈະໄດ້ຮັບສຳເນົາໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ

ສ່ວນທີ 1. ຂໍ້ມູນໂຄງການວິໄຈ

ຂ້າພະເຈົ້າຊື່ ດຣ. ແກ້ວບຸຜາພອນ ຈິນດາວົງສາ ເຮັດວຽກຢູ່ສູນໄຂ້ຍຸງ, ແມ່ກາຝາກ ແລະ ແມງໄມ້ກະຊວງສາທາລະນະສຸກ ຂ້າພະເຈົ້າກຳລັງດຳເນີນການສຶກສາປະສິດທິຜົນຂອງການປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍ. ພະຍາດນີ້ ແມ່ນພະຍາດອັນຕະລາຍ ແຕ່ກໍ່ສາມາປິ່ນປົວປົວໄດ້ດ້ວຍຢາ. ຈຸດປະສົງຂອງການສຶກສານີ້ເພື່ອເປັນການຢັ້ງຢັນວ່າ ຢາປະສົມອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ທີ່ໃຊ້ປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍຊະນິດ ຟານຊີປາລອມຍັງມີປະສິດທິພາບໃນການປິ່ນປົວໄດ້ດີຢູ່.

ຂ້າພະເຈົ້າຂໍເຊີນຄົນເຈັບທີ່ເປັນຜູ້ໃຫຍ່ທຸກຄົນ ແລະ ເດັກທີ່ມີອາຍຸ 6 ເດືອນຂຶ້ນໄປທີ່ດຳລົງຊີວິດໃນພື້ນທີ່ເປົ້າໝາຍຂອງການສຶກສານີ້.

ຂ້າພະເຈົ້າຂໍໃຫ້ຂໍ້ມູນກ່ຽວກັບການເຝົ້າລະວັງເຊື້ອໄຂ້ມາລາເຣຍຕ້ານຕ່ຢາ ແລະ ຂໍເຊື້ອເຊີນເຂົ້າຮ່ວມ ໃນການສຶກສາວິໄຈ. ກ່ອນທີ່ທ່ານຈະຕັດສິນໃຈເຂົ້າຮ່ວມ ທ່ານສາມາດສອບຖາມນຳໃຜກໍ່ໄດ້ທີ່ທ່ານໝໍໃຈ ເມື່ອທ່ານພົບບາງຄຳສັບ ຫຼື ຄຳຖາມບາງຄຳທີ່ທ່ານບໍ່ເຂົ້າໃຈ ເຊີນທ່ານສອບຖາມຂ້າພະເຈົ້າໄດ້ເລີຍ ເພື່ອອະທິບາຍຂໍ້ຄວາມ ຫຼື ຄຳເວົ້າຕ່າງໆນັ້ນໃຫ້ທ່ານເຂົ້າໃຈກ່ອນທີ່ຈະຜ່ານໄປຫາຂໍ້ມູນອື່ນໆ ຫຼື ທ່ານຍັງມີຂໍ້ສົງໄສພາຍຫຼັງທ່ານສາມາດກັບມາຖາມຂ້າພະເຈົ້າ ຫຼື ພະນັກງານທີ່ຮ່ວມໃນໂຄງການນີ້ເມື່ອໃດກໍ່ໄດ້.

ການເຂົ້າຮ່ວມຂອງທ່ານເປັນຄວາມສະມັກໃຈຂອງທ່ານເອງ. ທ່ານສາມາດເລືອກວ່າ ຈະເຂົ້າຮ່ວມ ຫຼື ບໍ່ເຂົ້າຮ່ວມກໍ່ໄດ້. ທ່ານຈະເລືອກແບບໃດກໍ່ຕາມ ທ່ານຍັງຈະໄດ້ຮັບການບໍລິການປິ່ນປົວເຊັ່ນກັບຄົນອື່ນ ແລະ ເຖິງວ່າທ່ານໄດ້ເລືອກເຂົ້າຮ່ວມໂຄງການແລ້ວ ທ່ານສາມາດທີ່ຈະຖອນຕົວເມື່ອໃດກໍ່ໄດ້.

ເມື່ອທ່ານຕັດສິນໃຈເຂົ້າໂຄງການ ທ່ານຈະໄດ້ຮັບຢາ ອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ຕາມຂໍ້ແນະນຳຂອງກະຊວງສາທາລະນະສຸກ ເພື່ອປິ່ນປົວໄຂ້ມາລາເຣຍຊະນິດ ຟານຊີປາລອມ ຈຳນວນ 3 ຄັ້ງ ເປັນເວລາ 3 ມື້ຕິດຕໍ່ກັນ. ຢານີ້ຜະລິດຈາກບໍລິສັດ Novartis Pharmaceuticals Istanbul, Turkey ທີ່ມີຊື່ທາງການຄ້າວ່າ Coartem® ຊຶ່ງມີຊື່ທາງການຄ້າວ່າ ໂກອັກແຕມ. ເຊັ່ນດຽວກັນກັບຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍ

[9] http://www.who.int/rpc/research_ethics/en/

ຊະນິດອື່ນ ຢາເຫຼົ່ານີ້ອາດພົບມີອາການຂ້າງຄຽງເລັກນ້ອຍເຊັ່ນ : ປວດຮາກ, ເຈັບທ້ອງ, ຫຼື ວິນຫົວ ເປັນຕົ້ນ. ອາການດັ່ງກ່າວແມ່ນເປັນໃນ ລະດັບເບົາບາງ ແລະ ຈະເຊົາໄປເອງໃນເວລາອັນສັ້ນ.

ຖ້າພວກເຮົາພົບວ່າ ຢາດັ່ງກ່າວປິ່ນປົວບໍ່ໄດ້ຜົນ ເຮົາຈະໃຊ້ຢາອັນດັບສອງປິ່ນປົວເຊັ່ນ : ຢາກິນິນ+ດີກຊີຊິກລິນ ເປັນເວລາ 7 ວັນຕິດຕໍ່ ກັນ ຕາມຂໍ້ແນະນຳໃນຄູ່ມືປິ່ນປົວແຫ່ງຊາດ. ທ່ານຄວນຮູ້ເອົາໄວ້ວ່າ ຢາດັ່ງກ່າວນີ້ອາດພາໃຫ້ມີອາການຂ້າງຄຽງເລັກນ້ອຍເຊັ່ນ :ຖອກທ້ອງ, ວິນຫົວ, ເຈັບຫົວ, ປວດຮາກ, ເມື່ອຍເພຍ, ປັ້ນທ້ອງ, ແລະຮາກ ແຕ່ອາການທັງໝົດນີ້ ເປັນບໍ່ແຮງ ແລະ ເຊົາໄວ.

ໂຄງການຈະໃຊ້ເວລາ 28 ວັນ. ໃນໄລຍະນີ້ ການເຂົ້າຮ່ວມໂຄງການນີ້ທ່ານຈະຕ້ອງມາ ປິ່ນປົວທີ່ສະຖານບໍລິການ ໃນ 3 ມື້ທຳອິກຢ່າງຕໍ່ ເນື່ອງ ຈາກນັ້ນ ກໍ່ມາກວດເລືອດຕິດຕາມ ໃນທຸກອາທິດ ອຂງ 4 ອາທິດທີ່ຍັງເຫຼືອ (ນັດໝາຍ 8 ຄັ້ງ) ຕາມຕາຕະລາງນັດໝາຍ. ການມາຕິດຕາມ ໃນອາທິດທີ 4 ຈະເປັນດານຕິດຕາມຄັ້ງສຸດທ້າຍ. ແຕ່ລະຄັ້ງທີ່ມາກວດຕິດຕາມ ທ່ານຈະໄດ້ພົບແພດ.

ມື້ນີ້ ພວກເຮົາຈະກວດເລືອດໃຫ້ທ່ານ ຈາກນັ້ນແມ່ນໃຫ້ຢາປິ່ນປົວ. ຄັ້ງຕໍ່ໄປ:

ມື້ທີ່ 2: ທ່ານຈະໄດ້ຮັບຢາມື້ທີ 2.

ມື້ທີ 3: ທ່ານຈະໄດ້ຮັບຢາເປັນມື້ທີ 3 ແລະ ຈະໄດ້ເຈາະເລືອດເພື່ອກວດ

ນັດໝາຍມື້ທີ 4, 5, 6, 7, 8 ທ່ານຈະໄດ້ເຈາະເລືອດເພື່ອກວດ .

ໃນການເຈາະເລືອດເພື່ອກວດແມ່ນຈະເຈາະຢູ່ປາຍນິ້ວມື. ທ່ານອາດເຈັບເລັກນ້ອຍ ແລະ ຢ້ານເວລາເຈາະເລືອດ ແຕ່ອາການເຈັບນັ້ນຈະ ເຊົາດີໃນ 1 ມື້. ແພດຈະເອົາເລືອດທີ່ໄດ້ຈາກທ່ານ ຢອດໃສ່ແຜ່ນແກ້ວເພື່ອເຮັດພາບເລືອດ ແລະ ເຈ້ຍຊັບເລືອດເພື່ອຈະກວດຫາເຊື້ອໄຂ້ມາລາ ເຣຍ. ຕົວຢ່າງເລືອດນີ້ ຈະນຳໃຊ້ເຂົ້າໃນການກວດການຊອກຫາເຊື້ອມາລາເຣຍ. ກວດເລືອດບາງຄັ້ງຈະເຮັດໃຫ້ພາຍຫຼັງຈົບການສຶກສານີ້ແລ້ວແຕ່ ບໍ່ມີຜົນຕໍ່ການຮັກສາໃນຄັ້ງນີ້ ແລະ ກວດເລືອດຂອງທ່ານຈະບໍ່ໄດ້ນຳໄປກວດຢ່າງອື່ນ .

ຖ້າຫາກທ່ານບໍ່ສາມາດມາຕິດຕາມຜົນຂອງການປິ່ນປົວຢູ່ສະຖານບໍລິການຕາມນັດໝາຍ ພວກເຮົາຈະລົງໄປຕິດຕາມຜົນຂອງການ ປິ່ນປົວທີ່ບ້ານຂອງທ່ານ .

ຢາທີ່ໃຊ້ໃນການປິ່ນປົວອາດມີຜົນຂ້າງຄຽງ. ແພດຈະໃຫ້ເບີໂທລະສັບທີ່ທ່ານສາມາດຕິດຕໍ່ໄດ້ເມື່ອທ່ານມີອາການຂ້າງຄຽງ ຫຼື ມີຄວາມ ກັງວົນໃດໜຶ່ງ. ແພດຈະຕິດຕາມໄກ້ຊິດເມື່ອເກີດມີອາການດັ່ງກ່າວ. ທ່ານສາມາດມາສະຖານບໍລິການພົບແພດ ຖ້າຕ້ອງການ. ເມື່ອມີອາການເຊັ່ນ ນັ້ນ ແພດຈະຈັດຢາປິ່ນປົວ ເພື່ອລົດອາການໃຫ້ໂດຍບໍ່ເສຍຄ່າໃຊ້ຈ່າຍ ຫຼື ຢຸດໃຫ້ການປິ່ນປົວໄຂ້ມາລາເຣຍທີ່ໃຊ້ໃນການສຶກສາໃນຄັ້ງນີ້. ແພດ ອາດຈະລົມກັບທ່ານເພີ່ມເຕີມ. ແພດ ແລະ ທ່ານຈະໄດ້ປຶກສາຫາລືຢ່າງໃກ້ສິດກ່ອນການດຳ ເນີນການອື່ນຕໍ່ໄປ .

ເມືອທ່ານຕັດສິນໃຈເຂົ້າຮ່ວມໂຄງການ ທ່ານຈະໄດ້ຮັບການປິ່ນປົວຕ່າງໆທີ່ກ່ຽວຂ້ອງກັບພະຍາດໄຂ້ມາລາເຣຍ ຫຼື ພະຍາດໄຂ້ມາລາ ເຣຍໂດຍທ່ານຈະບໍ່ໄດ້ເສຍຄ່າໃຊ້ຈ່າຍ. ການເຂົ້າຮ່ວມໂຄງການຂອງທ່ານ ຈະຊ່ວຍໃຫ້ເຮົາໝັ້ນໃຈໃນປະສິດທິພາບຂອງຢາປິ່ນປົວພະຍາດໄຂ້ ມາລາເຣຍ ແລະນັ້ນຈະເປັນຜົນປະໂຫຍດຕໍ່ຄົນເຈັບອື່ນໆໃນທ້ອງຖິ່ນຂອງທ່ານ. ທ່ານຈະໄດ້ຮັບ ການຊ່ວຍເຫຼືອຄ່າເດີນທາງໃນການມາຕິດຕາມ ຜົນຂອງການປິ່ນປົວແຕ່ລະຄັ້ງບໍ່ເກີນ 50,000 ກີບ.

ເຮົາຈະບໍ່ເປີດເຜີຍຂໍ້ມູນສ່ວນຕົວຂອງທ່ານໃຫ້ຄົນອື່ນຮູ້. ຂໍ້ມູນຈະເກັບເປັນຄວາມລັບ. ຂໍ້ມູນຂອງທ່ານທຸກອັນ ຈະຖືກກຳນົດເປັນ ລະຫັດ ແຕ່ບໍ່ໄດ້ລະບຸຊື່ຂອງທ່ານ ເຊິ່ງຄະນະຜູ້ວິໃຈເທົ່ານັ້ນທີ່ຈະຮູ້ລະຫັດນີ້ ແລະ ລະຫັດຈະຖືກເກັບໄວ້ໃນທີ່ປອດໄພ. ເຮົາຈະໃຫ້ທ່ານຮັບຮູ້ ຜົນການສຶກສານີ້ກ່ອນທີ່ຈະເຜີຍແຜ່ສູ່ສາທາລະນະ ຈະບໍ່ມີການເຜີຍແຜ່ຂໍ້ມູນທີ່ເປັນສ່ວນຕົວຂອງທ່ານ. ຈະມີການນຳສະເໜີຜົນການສຶກສາໃຫ້ ໜ່ວຍງານສາທາລະນະສຸກໃນຂັ້ນເມືອງຂອງທ່ານຮັບຮູ້ ແລະ ເຜີຍແຜ່ໃຫ້ຜູ້ທີ່ສົນໃຈອື່ນຮັບຮູ້.

ບົດສະເໜີໂຄງການນີ້ ໄດ້ຮັບການທົບທວນ ແລະ ອະນຸມັດໃຫ້ດຳເນີນການໄດ້ໂດຍຄະນະກຳມະການຈັນຍາທຳແຫ່ງຊາດ ສະຖາບັນ ສາທາລະນະສຸກສາດ ກະຊວງສາທາລະນະສຸກ. ຄະນະກຳມະການຊຸດນີ້ມີໜ້າທີ່ຄຸ້ມຄອງອາສາສະມັກທີ່ເຂົ້າຮ່ວມໂຄງການສຶກສາ ໃຫ້ມີຄວາມ ປອດໄພ.

ສ່ວນທີ 2. ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ

ຂ້າພະເຈົ້າໄດ້ຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມໂຄງການສຶກສາປະສິດທິພາບຂອງຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍ. ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ຜູ້ວິໄຈໄດ້ອ່ານລາຍລະອຽດຂອງໂຄງການໃຫ້ຂ້າພະເຈົ້າຟັງ ພ້ອມໄດ້ສອບຖາມຂໍ້ສົງໄສ ແລະ ໄດ້ຄຳຕອບ ແລະ ອະທິບາຍຈົນເຮັດໃຫ້ຂ້າພະເຈົ້າເຂົ້າໃຈ, ຂ້າພະເຈົ້າຈຶ່ງຍິນດີເຂົ້າຮ່ວມໂຄງການນີ້.

ຊື່ອາສາສະມັກ: _____

ລາຍເຊັນອາສາສະມັກ: _____

ວັນທີ່: _____
(ວັນ/ເດືອນ/ປີ)

ລາຍເຊັນພະຍານ: (ຈຳເປັນຕ້ອງມີລາຍເຊັນພະຍານ ຫຼື ພິມລາຍນິ້ວມືຂອງຄົນເຈັບສະເພາະ ຖ້າຄົນເຈັບອ່ານ ຫຼື ຂຽນໜັງສືບໍ່ເປັນ. ພະຍານທີ່ສາມາດອ່ານອອກຂຽນໄດ້ ພະຍາກຈະຕ້ອງເຊັນໃນເອກະສານ. ຖ້າເປັນໄປໄດ້, ພະຍານຄວນປັນບຸກຄົນ ທີ່ຄົນເຈັບຄັດເລືອກເອງ ແລະ ບໍ່ມີສ່ວນກ່ຽວຂ້ອງກັບຄະນະວິໄຈ.

ຂ້າພະເຈົ້າຂໍເປັນພະຍານວ່າອາສາສະມັກໄດ້ຮັບຮູ້ຂໍ້ມູນໃນໃບຍິນຍອມ ແລະ ໄດ້ສອບຖາມຂໍ້ສົງໃສ ແລະ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ຊື່ພະຍານ: _____

ລາຍເຊັນພະຍານ: _____

ວັນທີ່: _____
(ວັນ/ເດືອນ/ປີ)

ພິມລາຍມື ຂອງຜູ້ເຂົ້າຮ່ວມໃນຫ້ອງນີ້

ລາຍເຊັນຜູ້ວິໄຈ:

ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ເປັນພະຍານໃນການອ່ານໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການໃຫ້ອາສາສະມັກຟັງ ອາສາສະມັກໄດ້ສອບຖາມຂໍ້ສົງໄສ ຂ້າພະເຈົ້າຂໍຢັ້ງຢືນວ່າ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ຊື່ຜູ້ວິໄຈ: _____

ລາຍເຊັນຜູ້ວິໄຈ: _____

ວັນທີ່: _____
(ວັນ/ເດືອນ/ປີ)

ອາສາສະມັກຈະໄດ້ຮັບສຳເນົາໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ 1 ສະບັບ _____(ຊື່ຂອງຜູ້ວິໄຈຫຼັກ ຫຼື ຜູ້ຊ່ວຍວິໄຈ)

ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການສຳລັບເດັກ

ແບບຟອມໃບຍິນຍອມນີ້ ໃຊ້ສຳລັບຜູ້ປົກຄອງ ຫຼື ຜູ້ດູແລເດັກ ອາຍຸ 6 ເດືອນ ຫຼື ຫຼາຍກ່ວາ ທີ່ເຂົ້າມາໃຊ້ບໍລິການຢູ່..... (ຊື່ໂຮງໝໍ) ໄດ້ຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມການສຶກສາປະສິດທິພາບຂອງຢາ ອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ສຳຫຼັບປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍຊະນິດຟານຊິປາລອມ ຫຼື ວິວັກ.

ຊື່ຫົວໜ້າທີມວິໄຈ:	ດຣ. ແກ້ວບຸຜາພອນ ຈິນດາວົງສາ
ຊື່ສະຖານທີເຮັດວຽກ:	ສູນໄຂ້ຍຸງ, ແມ່ກາຝາກ ແລະ ແມງໄມ້
ຊື່ອົງການສະໜັບສະໜູນ:	ກະຊວງສາທາລະນະສຸກ
ຊື່ບົດສະເໜີໂຄງການ:	Lao 1/2022

ແບບຍິນຍອມໃຫ້ເຮັດການສຶກສາວິໄຈນີ້ປະກອບດ້ວຍ 2 ສ່ວນ:

1. ຂໍ້ມູນກ່ຽວກັບການສຶກສາວິໄຈ
2. ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ (ສຳຫຼັບຄົນເຈັບທີເຂົ້າຮ່ວມ ຈະໄດ້ເຊັນ ແລະ ຮັບສຳເນົາໃບຍິນຍອມ)

ສ່ວນທີ 1. ຂໍ້ມູນໂຄງການວິໄຈ

ຂ້າພະເຈົ້າຊື່ ດຣ. ແກ້ວບຸຜາພອນ ຈິນດາວົງສາ ເຮັດວຽກຢູ່ສູນໄຂ້ຍຸງ, ແມ່ກາຝາກ ແລະ ແມງໄມ້ກະຊວງສາທາລະນະສຸກ ຂ້າພະເຈົ້າ ກຳລັງດຳເນີນການສຶກສາປະສິດທິຜົນຂອງການປິ່ນປົວຄົນເຈັບທີເປັນພະຍາດໄຂ້ມາລາເຣຍ. ພະຍາດນີ້ ແມ່ນພະຍາດອັນຕະລາຍ ແຕ່ກໍ່ສາມາປິ່ນປົວປົວໄດ້ດ້ວຍຢາ. ຈຸດປະສົງຂອງການສຶກສານີ້ເພື່ອເປັນການຢັ້ງຢືນວ່າ ຢາປະສົມອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ທີ່ໃຊ້ປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍຊະນິດ ຟານຊິປາລອມຍັງມີປະສິດທິພາບໃນການປິ່ນປົວໄດ້ດີຢູ່.

ຂ້າພະເຈົ້າຂໍເຊີນຄົນເຈັບທີ່ເປັນຜູ້ໃຫຍ່ທຸກຄົນ ແລະ ເດັກທີ່ມີອາຍຸ 6 ເດືອນຂຶ້ນໄປທີ່ດຳລົງຊີວິດໃນພື້ນທີ່ເປົ້າໝາຍຂອງການສຶກສານີ້.

ຂ້າພະເຈົ້າຂໍໃຫ້ຂໍ້ມູນກ່ຽວກັບການເຝົ້າລະວັງເຊື້ອໄຂ້ມາລາເຣຍຕ້ານຕ່ຢາ ແລະ ຂໍເຊື້ອເຊີນເຂົ້າຮ່ວມ ໃນການສຶກສາວິໄຈ. ກ່ອນທີ່ທ່ານຈະຕັດສິນໃຈເຂົ້າຮ່ວມ ທ່ານສາມາດສອບຖາມນຳໃຜກໍ່ໄດ້ທີ່ທ່ານພໍໃຈ ເມື່ອທ່ານພົບບາງຄຳສັບ ຫຼື ຄຳຖາມບາງຄຳທີ່ທ່ານບໍ່ເຂົ້າໃຈ ເຊີນທ່ານສອບຖາມຂ້າພະເຈົ້າໄດ້ເລີຍ ເພື່ອອະທິບາຍຂໍ້ຄວາມ ຫຼື ຄຳເວົ້າຕ່າງໆນັ້ນໃຫ້ທ່ານເຂົ້າໃຈກ່ອນທີ່ຈະຜ່ານໄປຫາຂໍ້ມູນອື່ນໆ ຫຼື ທ່ານຍັງມີຂໍ້ສົງໄສ ພາຍຫຼັງທ່ານສາມາດກັບມາຖາມຂ້າພະເຈົ້າ ຫຼື ພະນັກງານທີ່ຮ່ວມໃນໂຄງການນີ້ເມື່ອໃດກໍ່ໄດ້.

ການທີ່ເດັກເຂົ້າຮ່ວມ ເປັນຄວາມສະມັກໃຈຂອງທ່ານເອງ. ທ່ານສາມາດເລືອກວ່າ ຈະເຂົ້າຮ່ວມ ຫຼື ບໍ່ເຂົ້າຮ່ວມກໍ່ໄດ້. ທ່ານຈະເລືອກແບບໃດກໍ່ຕາມ ລູກຂອງທ່ານຍັງຈະໄດ້ຮັບການບໍລິການປິ່ນປົວເຊັ່ນກັບຄົນອື່ນ ແລະ ເຖິງວ່າທ່ານໄດ້ເລືອກເຂົ້າຮ່ວມໂຄງການແລ້ວ ທ່ານສາມາດທີ່ຈະຖອນຕົວເມື່ອໃດກໍ່ໄດ້.

ເມື່ອລູກທ່ານໄດ້ເຂົ້າຮ່ວມໂຄງການ ເດັກຈະໄດ້ຮັບຢາ ອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ຕາມຂໍ້ແນະນຳຂອງກະຊວງສາທາລະນະສຸກ ເພື່ອປິ່ນປົວໄຂ້ມາລາເຣຍຊະນິດ ຟານຊິປາລອມ ຈຳນວນ 3 ຄັ້ງ ເປັນເວລາ 3 ມື້ຕິດຕໍ່ກັນ. ຢານີ້ຜະລິດຈາກບໍລິສັດ Novartis Pharmaceuticals Istanbul, Turkey ທີ່ມີຊື່ທາງການຄ້າວ່າ Coartem®. ເຊັ່ນດຽວກັນກັບຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍຊະນິດອື່ນ ຢາເຫຼົ່ານີ້ອາດພົບມີອາການຂ້າງຄຽງເລັກນ້ອຍເຊັ່ນ : ປວດຮາກ, ເຈັບທ້ອງ, ຫຼື ວິນຫົວ ເປັນຕົ້ນ. ອາການດັ່ງກ່າວແມ່ນເປັນໃນລະດັບເບົາບາງ ແລະ ຈະເຊົາໄປເອງ ໃນເວລາອັນສັ້ນ.

ຖ້າພວກເຮົາພົບວ່າ ຢາດັ່ງກ່າວປິ່ນປົວບໍ່ໄດ້ຜົນ ເຮົາຈະໃຊ້ຢາອັນດັບສອງປິ່ນປົວເຊັ່ນ : ຢາກິນິນ+ດັກຊີຊິກລິນ ເປັນເວລາ 7 ວັນຕິດຕໍ່ກັນ ຕາມຂໍ້ແນະນຳໃນຄູ່ມືປິ່ນປົວແຫ່ງຊາດ. ທ່ານຄວນຮູ້ເອົາໄວ້ວ່າ ຢາດັ່ງກ່າວນີ້ອາດພາໃຫ້ມີອາການຂ້າງຄຽງເລັກນ້ອຍເຊັ່ນ :ຖອກທ້ອງ, ວິນຫົວ, ເຈັບຫົວ, ປວດຮາກ, ເມື່ອຍເພຍ, ປັ້ນທ້ອງ, ແລະຮາກ ແຕ່ອາການທັງໝົດນີ້ ເປັນບໍ່ແຮງ ແລະ ເຊົາໄວ.

ໂຄງການຈະໃຊ້ເວລາ 28 ວັນ. ໃນໄລຍະນີ້ ການເຂົ້າຮ່ວມໂຄງການນີ້ທ່ານຈະຕ້ອງມາ ປິ່ນປົວທີ່ສະຖານບໍລິການ ໃນ 3 ມື້ທຳອິກຢ່າງຕໍ່ເນື່ອງ ຈາກນັ້ນ ກໍ່ມາກວດເລືອດຕິດຕາມ ໃນທຸກອາທິດ ອຂ 4 ອາທິດທີ່ຍັງເຫຼືອ (ນັດໝາຍ 8 ຄັ້ງ) ຕາມຕາຕະລາງນັດໝາຍ. ການມາຕິດຕາມໃນອາທິດທີ 4 ຈະເປັນການຕິດຕາມຄັ້ງສຸດທ້າຍ. ແຕ່ລະຄັ້ງທີ່ມາກວດຕິດຕາມ ທ່ານຈະໄດ້ພົບແພດ.

ມື້ນີ້ ພວກເຮົາຈະກວດເລືອດໃຫ້ທ່ານ ຈາກນັ້ນແມ່ນໃຫ້ຢາປິ່ນປົວ. ຄັ້ງຕໍ່ໄປ:

ມື້ທີ່ 2: ທ່ານຈະໄດ້ຮັບຢາມື້ທີ 2.

ມື້ທີ 3: ທ່ານຈະໄດ້ຮັບຢາເປັນມື້ທີ 3 ແລະ ຈະໄດ້ເຈາະເລືອດເພື່ອກວດ

ນັດໝາຍມື້ທີ 4, 5, 6, 7, 8 ທ່ານຈະໄດ້ເຈາະເລືອດເພື່ອກວດ .

ໃນການເຈາະເລືອດເພື່ອກວດແມ່ນຈະເຈາະຢູ່ປາຍນິ້ວມື. ເດັກອາດເຈັບເລັກນ້ອຍ ແລະ ຢ້ານເວລາເຈາະເລືອດ ແຕ່ອາການເຈັບນັ້ນຈະເຊົາດີໃນ 1 ມື້. ແພດຈະເອົາເລືອດທີ່ໄດ້ຈາກເດັກ ຢອດໃສ່ແຜ່ນແກ້ວເພື່ອເຮັດພາບເລືອດ ແລະ ເຈ້ຍຊັບເລືອດເພື່ອຈະກວດຫາເຊື້ອໄຂ້ມາລາເຣຍ. ຕົວຢ່າງເລືອດນີ້ ຈະນຳໃຊ້ເຂົ້າໃນການກວດການຊອກຫາເຊື້ອມາລາເຣຍ. ກວດເລືອດບາງຄັ້ງຈະເຮັດໃຫ້ພາຍຫຼັງຈົບການສຶກສານີ້ແລ້ວແຕ່ ບໍ່ມີຜົນຕໍ່ການຮັກສາໃນຄັ້ງນີ້ ແລະ ກວດເລືອດຂອງເດັກຈະບໍ່ໄດ້ນຳໄປກວດຢ່າງອື່ນ .

ຖ້າຫາກທ່ານບໍ່ສາມາດມາຕິດຕາມຜົນຂອງການປິ່ນປົວຢູ່ສະຖານບໍລິການຕາມນັດໝາຍ ພວກເຮົາຈະລົງໄປຕິດຕາມຜົນຂອງການປິ່ນປົວຂອງເດັກທີ່ບ້ານຂອງທ່ານ .

ຢາທີ່ໃຊ້ໃນການປິ່ນປົວອາດມີຜົນຂ້າງຄຽງ. ແພດຈະໃຫ້ເບີໂທລະສັບທີ່ທ່ານສາມາດຕິດຕໍ່ໄດ້ເມື່ອທ່ານມີອາການຂ້າງຄຽງ ຫຼື ມີຄວາມກັງວົນໃດໜຶ່ງ. ແພດຈະຕິດຕາມໄກ້ຊິດເມື່ອເກີດມີອາການດັ່ງກ່າວ. ທ່ານສາມາດມາສະຖານບໍລິການພົບແພດ ຖ້າຕ້ອງການ. ເມື່ອມີອາການເຊັ່ນນັ້ນ ແພດຈະຈັດຢາປິ່ນປົວ ເພື່ອລົດອາການໃຫ້ໂດຍບໍ່ເສຍຄ່າໃຊ້ຈ່າຍ ຫຼື ຢຸດໃຫ້ການປິ່ນປົວໄຂ້ມາລາເຣຍທີ່ໃຊ້ໃນການສຶກສາໃນຄັ້ງນີ້. ແພດອາດຈະລົມກັບທ່ານເພີ່ມເຕີມ. ແພດ ແລະ ທ່ານຈະໄດ້ປຶກສາຫາລືຢ່າງໃກ້ສິດກ່ອນການດຳ ເນີນການອື່ນຕໍ່ໄປ .

ເມື່ອທ່ານຕັດສິນໃຈເຂົ້າຮ່ວມໂຄງການ ທ່ານຈະໄດ້ຮັບການປິ່ນປົວຕ່າງໆທີ່ກ່ຽວຂ້ອງກັບພະຍາດໄຂ້ມາລາເຣຍ ຫຼື ພະຍາດໄຂ້ມາລາເຣຍໂດຍທ່ານຈະບໍ່ໄດ້ເສຍຄ່າໃຊ້ຈ່າຍ. ການເຂົ້າຮ່ວມໂຄງການຂອງທ່ານ ຈະຊ່ວຍໃຫ້ເຮົາໝັ້ນໃຈໃນປະສິດທິພາບຂອງຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍ ແລະນັ້ນຈະເປັນຜົນປະໂຫຍດຕໍ່ຄົນເຈັບອື່ນໆໃນທ້ອງຖິ່ນຂອງທ່ານ. ທ່ານຈະໄດ້ຮັບ ການຊ່ວຍເຫຼືອຄ່າເດີນທາງໃນການມາຕິດຕາມຜົນຂອງການປິ່ນປົວແຕ່ລະຄັ້ງບໍ່ເກີນ 50,000 ກີບ.

ເຮົາຈະບໍ່ເປີດເຜີຍຂໍ້ມູນສ່ວນຕົວຂອງເດັກໃຫ້ຄົນອື່ນຮູ້. ຂໍ້ມູນຈະເກັບເປັນຄວາມລັບ. ຂໍ້ມູນຂອງເດັກທຸກອັນ ຈະຖືກກຳນົດເປັນລະຫັດ ແຕ່ບໍ່ໄດ້ລະບຸຊື່ຂອງເດັກ ເຊິ່ງຄະນະຜູ້ວິໃຈເທົ່ານັ້ນທີ່ຈະຮູ້ລະຫັດນີ້ ແລະ ລະຫັດຈະຖືກເກັບໄວ້ໃນທີ່ປອດໄພ. ເຮົາຈະໃຫ້ທ່ານຮັບຮູ້ຜົນການສຶກສານີ້ກ່ອນທີ່ຈະເຜີຍແຜ່ສູ່ສາທາລະນະ ຈະບໍ່ມີການເຜີຍແຜ່ຂໍ້ມູນທີ່ເປັນສ່ວນຕົວຂອງເດັກ. ຈະມີການນຳສະເໜີຜົນການສຶກສາໃຫ້ໜ່ວຍງານສາທາລະນະສຸກໃນຂັ້ນເມືອງຂອງທ່ານຮັບຮູ້ ແລະ ເຜີຍແຜ່ໃຫ້ຜູ້ທີ່ສົນໃຈອື່ນຮັບຮູ້.

ບົດສະເໜີໂຄງການນີ້ ໄດ້ຮັບການທົບທວນ ແລະ ອະນຸມັດໃຫ້ດຳເນີນການໄດ້ໂດຍຄະນະກຳມະການຈັນຍາທຳແຫ່ງຊາດ ສະຖາບັນສາທາລະນະສຸກສາດ ກະຊວງສາທາລະນະສຸກ. ຄະນະກຳມະການຊຸດນີ້ມີໜ້າທີ່ຄຸ້ມຄອງອາສາສະມັກທີ່ເຂົ້າຮ່ວມໂຄງການສຶກສາ ໃຫ້ມີຄວາມປອດໄພ.

ສ່ວນທີ 2. ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ

ຂ້າພະເຈົ້າໄດ້ຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມໂຄງການສຶກສາປະສິດທິພາບຂອງຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍ. ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ຜູ້ວິໃຈໄດ້ອ່ານລາຍລະອຽດຂອງໂຄງການໃຫ້ຂ້າພະເຈົ້າຟັງ ພ້ອມໄດ້ສອບຖາມຂໍ້ສົງໄສ ແລະ ໄດ້ຄຳຕອບ ແລະ ອະທິບາຍຈົນເຮັດໃຫ້ຂ້າພະເຈົ້າເຂົ້າໃຈ, ຂ້າພະເຈົ້າຈຶ່ງຍິນດີເຂົ້າຮ່ວມໂຄງການນີ້.

ຊື່ອາສາສະມັກ: _____

ລາຍເຊັນອາສາສະມັກ: _____

ວັນທີ: _____

(ວັນ/ເດືອນ/ປີ)

ລາຍເຊັນພະຍານ: (ຈຳເປັນຕ້ອງມີລາຍເຊັນພະຍານ ຫຼື ພິມລາຍນິ້ວມືຂອງຄົນເຈັບສະເພາະ ຖ້າຄົນເຈັບອ່ານ ຫຼື ຂຽນໜັງສືບໍ່ເປັນ. ພະຍານທີ່ສາມາດອ່ານອອກຂຽນໄດ້ ພະຍາກຈະຕ້ອງເຊັນໃນເອກະສານ. ຖ້າເປັນໄປໄດ້, ພະຍານຄວນປັນບຸກຄົນ ທີ່ຄົນເຈັບຄັດເລືອກເອງ ແລະ ບໍ່ມີສ່ວນກ່ຽວຂ້ອງກັບຄະນະວິໄຈ.

ຂ້າພະເຈົ້າຂໍເປັນພະຍານວ່າອາສາສະມັກໄດ້ຮັບຮູ້ຂໍ້ມູນໃນໃບຍິນຍອມ ແລະ ໄດ້ສອບຖາມຂໍ້ສົງໃສ ແລະ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ພິມລາຍມື ຂອງຜູ້ເຂົ້າຮ່ວມໃນຫ້ອງນີ້

ຊື່ພະຍານ: _____

ລາຍເຊັນພະຍານ: _____

ວັນທີ່: _____
(ວັນ/ເດືອນ/ປີ)

ລາຍເຊັນຜູ້ວິໄຈ:

ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ເປັນພະຍານໃນການອ່ານໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການໃຫ້ຜູ້ປົກຄອງຂອງອາສາສະມັກຟັງ ຊຶ່ງຜູ້ປົກຄອງ ໄດ້ສອບຖາມຂໍ້ສົງໄສ ຂ້າພະເຈົ້າຂໍຢັ້ງຢືນວ່າ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ຊື່ຜູ້ວິໄຈ: _____

ລາຍເຊັນຜູ້ວິໄຈ: _____

ວັນທີ່: _____
(ວັນ/ເດືອນ/ປີ)

ອາສາສະມັກຈະໄດ້ຮັບສຳເນົາໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ 1 ສະບັບ _____(ຊື່ຂອງຜູ້ວິໄຈຫຼັກ ຫຼື ຜູ້ຊ່ວຍວິໄຈ)

ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການສຳລັບເດັກອາຍຸ 12-14 ປີ

ແບບຟອມໃບຍິນຍອມນີ້ ໃຊ້ເດັກ ອາຍຸ 12-18 ປີ ທີ່ເຂົ້າມາໃຊ້ບໍລິການຢູ່.....(ຊື່ໂຮງໝໍ) ໄດ້ຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມການສຶກສາປະສິດທິພາບຂອງຢາ ອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ສຳຫຼັບປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍຊະນິດຟານຊີປາລອມ ຫຼື ວີວັກ.

ຊື່ຫົວໜ້າທີມວິໄຈ:	ດຣ. ແກ້ວບຸຜາພອນ ຈິນດາວົງສາ
ຊື່ສະຖານທີເຮັດວຽກ:	ສູນໄຂ້ຍຸງ, ແມ່ກາຝາກ ແລະ ແມງໄມ້
ຊື່ອົງການສະໜັບສະໜູນ:	ກະຊວງສາທາລະນະສຸກ
ຊື່ບົດສະເໜີໂຄງການ:	Lao 1/2022

ແບບຍິນຍອມໃຫ້ເຮັດການສຶກສາວິໄຈນີ້ປະກອບດ້ວຍ 2 ສ່ວນ:

1. ຂໍ້ມູນກ່ຽວກັບການສຶກສາວິໄຈ
2. ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ (ສຳຫຼັບຄົນເຈັບທີເຂົ້າຮ່ວມ ຈະໄດ້ເຊັນ ແລະ ຮັບສຳເນົາໃບຍິນຍອມ)

ສ່ວນທີ 1. ຂໍ້ມູນໂຄງການວິໄຈ

ຂ້າພະເຈົ້າຊື່ ດຣ. ແກ້ວບຸຜາພອນ ຈິນດາວົງສາ ເຮັດວຽກຢູ່ສູນໄຂ້ຍຸງ, ແມ່ກາຝາກ ແລະ ແມງໄມ້ກະຊວງສາທາລະນະສຸກ ຂ້າພະເຈົ້າກຳລັງດຳເນີນການສຶກສາປະສິດທິຜົນຂອງການປິ່ນປົວຄົນເຈັບທີເປັນພະຍາດໄຂ້ມາລາເຣຍ. ພະຍາດນີ້ ແມ່ນພະຍາດອັນຕະລາຍ ແຕ່ກໍ່ສາມາປິ່ນປົວປົວໄດ້ດ້ວຍຢາ. ຈຸດປະສົງຂອງການສຶກສານີ້ເພື່ອເປັນການຢັ້ງຢັນວ່າ ຢາປະສົມອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ທີ່ໃຊ້ປິ່ນປົວຄົນເຈັບທີ່ເປັນພະຍາດໄຂ້ມາລາເຣຍຊະນິດ ຟານຊີປາລອມຍັງມີປະສິດທິພາບໃນການປິ່ນປົວໄດ້ດີຢູ່.

ຂ້າພະເຈົ້າຂໍເຊີນຄົນເຈັບທີ່ເປັນຜູ້ໃຫຍ່ທຸກຄົນ ແລະ ເດັກທີ່ມີອາຍຸ 12-14 ປີ ທີ່ດຳລົງຊີວິດໃນພື້ນທີ່ເປົ້າໝາຍຂອງການສຶກສານີ້.

ຂ້າພະເຈົ້າຂໍໃຫ້ຂໍ້ມູນກ່ຽວກັບການເຝົ້າລະວັງເຊື້ອໄຂ້ມາລາເຣຍຕ້ານຕ່ຢາ ແລະ ຂໍເຊື້ອເຊີນເຂົ້າຮ່ວມ ໃນການສຶກສາວິໄຈກັບຜູ້ປົກຄອງທ່ານເພື່ອອະນຸຍາດເຂົ້າຮ່ວມ. ຖ້າທ່ານຕັດສິນໃຈທີ່ຈະເຂົ້າຮ່ວມ ຜູ້ປົກຄອງຂອງທ່ານຕ້ອງອະນຸຍາດຄືກັນ. ຖ້າທ່ານບໍ່ຢາກເຂົ້າຮ່ວມ ທ່ານບໍ່ເຂົ້າກໍ່ໄດ້ ເຖິງວ່າພໍ່ແມ່ຈະອະນຸຍາດກໍ່ຕາມ ແຕ່ໂຮງໝໍຮ່ວມຫ່ານນີ້ ຍັງຄົງເປັນສະຖານທີ່ ທີ່ຈະບໍລິການທ່ານຄືເກົ່າ. ກ່ອນທີ່ທ່ານຈະຕັດສິນໃຈເຂົ້າຮ່ວມ ທ່ານສາມາດສອບຖາມນຳໃຜກໍ່ໄດ້ທີ່ທ່ານພໍໃຈ ເມື່ອທ່ານພົບບາງຄຳສັບ ຫຼື ຄຳຖາມບາງຄຳທີ່ທ່ານບໍ່ເຂົ້າໃຈ ເຊີນທ່ານ ສອບຖາມ ຂ້າພະເຈົ້າໄດ້ເລີຍ ເພື່ອອະທິບາຍຂໍ້ຄວາມ ຫຼື ຄຳເວົ້າຕ່າງໆນັ້ນໃຫ້ທ່ານເຂົ້າໃຈກ່ອນທີ່ຈະຜ່ານໄປຫາຂໍ້ມູນອື່ນໆ ຫຼື ທ່ານຍັງມີຂໍ້ສົງໄສພາຍຫຼັງ ທ່ານສາມາດກັບມາຖາມຂ້າພະເຈົ້າ ຫຼື ພະນັກງານທີ່ຮ່ວມໃນໂຄງການນີ້ເມື່ອໃດກໍ່ໄດ້.

ການທີ່ເດັກເຂົ້າຮ່ວມ ເປັນຄວາມສະມັກໃຈຂອງທ່ານເອງ. ທ່ານສາມາດເລືອກວ່າ ຈະເຂົ້າຮ່ວມ ຫຼື ບໍ່ເຂົ້າຮ່ວມກໍ່ໄດ້. ທ່ານຈະເລືອກແບບໃດກໍ່ຕາມ ລູກຂອງທ່ານຍັງຈະໄດ້ຮັບການບໍລິການປິ່ນປົວເຊັ່ນກັບຄົນອື່ນ ແລະ ເຖິງວ່າທ່ານໄດ້ເລືອກເຂົ້າຮ່ວມໂຄງການແລ້ວ ທ່ານສາມາດທີ່ຈະຖອນຕົວເມື່ອໃດກໍ່ໄດ້.

<u>ຜູ້ສຳພາດ</u>: ຂ້າພະເຈົ້າໄດ້ກວດສອບ ແລະ ສອບຖາມເດັກ ຊຶ່ງລາວເຂົ້າໃຈ ແລະ ເຂົ້າຮ່ວມການສຶກສາແບບສະໝັກໃຈ. ເຊັນ.....

ເມື່ອເດັກຕັດສິນໃຈເຂົ້າຮ່ວມໂຄງການ ເດັກຈະໄດ້ຮັບຢາ ອາເຕມິເຕ-ລຸຍເມຟັງຕິນ ຕາມຂໍ້ແນະນຳຂອງກະຊວງສາທາລະນະສຸກ ເພື່ອປິ່ນປົວໄຂ້ມາລາເຣຍຊະນິດ ຟານຊີປາລອມ ຈຳນວນ 3 ຄັ້ງ ເປັນເວລາ 3 ມື້ຕິດຕ່ໍກັນ. ຢານີ້ຜະລິດຈາກບໍລິສັດ Novartis Pharmaceuticals Istanbul, Turkey ທີ່ມີຊື່ທາງການຄ້າວ່າ Coartem®. ເຊັ່ນດຽວກັນກັບຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍຊະນິດອື່ນ ຢາເຫຼົ່ານີ້ອາດພົບມີອາການຂ້າງຄຽງເລັກນ້ອຍເຊັ່ນ : ປວດຮາກ, ເຈັບທ້ອງ, ຫຼື ວິນຫົວ ເປັນຕົ້ນ. ອາການດັ່ງກ່າວແມ່ນເປັນໃນລະດັບເບົາບາງ ແລະ ຈະເຊົາໄປເອງ ໃນເວລາອັນສັ້ນ.

ຖ້າພວກເຮົາພົບວ່າ ຢາດັ່ງກ່າວປິ່ນປົວບໍ່ໄດ້ຜົນ ເຮົາຈະໃຊ້ຢາອັນດັບສອງປິ່ນປົວເຊັ່ນ : ຢາກິນິນ+ດັກຊີຊິກລິນ ເປັນເວລາ 7 ວັນຕິດຕໍ່ກັນ ຕາມຂໍ້ແນະນຳໃນຄູ່ມືປິ່ນປົວແຫ່ງຊາດ. ທ່ານຄວນຮູ້ເອົາໄວ້ວ່າ ຢາດັ່ງກ່າວນີ້ອາດພາໃຫ້ມີອາການຂ້າງຄຽງເລັກນ້ອຍເຊັ່ນ :ຖອກທ້ອງ, ວິນຫົວ, ເຈັບຫົວ, ປວດຮາກ, ເມື່ອຍເພຍ, ປັ້ນທ້ອງ, ແລະຮາກ ແຕ່ອາການທັ້ງໝົດນີ້ ເປັນບໍ່ແຮງ ແລະ ເຊົາໄວ.

ໂຄງການຈະໃຊ້ເວລາ 28 ວັນ. ໃນໄລຍະນີ້ ການເຂົ້າຮ່ວມໂຄງການນີ້ທ່ານຈະຕ້ອງມາ ປິ່ນປົວທີ່ສະຖານບໍລິການ ໃນ 3 ມື້ທຳອິກຢ່າງຕໍ່ເນື່ອງ ຈາກນັ້ນ ກໍ່ມາກວດເລືອດຕິດຕາມ ໃນທຸກອາທິດ ຂອງ 4 ອາທິດທີ່ຍັງເຫຼືອ (ນັດໝາຍ 8 ຄັ້ງ) ຕາມຕາຕະລາງນັດໝາຍ. ການມາຕິດຕາມໃນອາທິດທີ 4 ຈະເປັນການຕິດຕາມຄັ້ງສຸດທ້າຍ. ແຕ່ລະຄັ້ງທີ່ມາກວດຕິດຕາມ ທ່ານຈະໄດ້ພົບແພດ.

ໃນການເຈາະເລືອດເພື່ອກວດແມ່ນຈະເຈາະຢູ່ປາຍນິ້ວມື. ເດັກອາດເຈັບເລັກນ້ອຍ ແລະ ຢ້ານເວລາເຈາະເລືອດ ແຕ່ອາການເຈັບນັ້ນຈະເຊົາດີໃນ 1 ມື້. ແພດຈະເອົາເລືອດທີ່ໄດ້ຈາກເດັກ ຢອດໃສ່ແຜ່ນແກ້ວເພື່ອເຮັດພາບເລືອດ ແລະ ເຈ້ຍຊັບເລືອດເພື່ອຈະກວດຫາເຊື້ອໄຂ້ມາລາເຣຍ. ຕົວຢ່າງເລືອດນີ້ ຈະນຳໃຊ້ເຂົ້າໃນການກວດການຊອກຫາເຊື້ອມາລາເຣຍ. ກວດເລືອດບາງຄັ້ງຈະເຮັດໃຫ້ພາຍຫຼັງຈົບການສຶກສານີ້ແລ້ວແຕ່ ບໍ່ມີຜົນຕໍ່ການຮັກສາໃນຄັ້ງນີ້ ແລະ ກວດເລືອດຂອງເດັກຈະບໍ່ໄດ້ນຳໄປກວດຢ່າງອື່ນ .

<u>ຜູ້ສຳພາດ</u>: ຂ້າພະເຈົ້າໄດ້ກວດສອບ ແລະ ສອບຖາມເດັກ ຊຶ່ງລາວເຂົ້າໃຈ ແລະ ເຂົ້າຮ່ວມການສຶກສາແບບສະໝັກໃຈ. ເຊັນ.....

ຢາທີ່ໃຊ້ໃນການປິ່ນປົວອາດມີຜົນຂ້າງຄຽງ. ແພດຈະໃຫ້ເບີໂທລະສັບທີ່ທ່ານສາມາດຕິດຕໍ່ໄດ້ເມື່ອທ່ານມີອາການຂ້າງຄຽງ ຫຼື ມີຄວາມກັງວົນໃດໜຶ່ງ. ແພດຈະຕິດຕາມໄກ້ຊິດເມື່ອເກີດມີອາການດັ່ງກ່າວ. ທ່ານສາມາດມາສະຖານບໍລິການພົບແພດ ຖ້າຕ້ອງການ. ເມື່ອມີອາການເຊັ່ນນັ້ນ ບໍ່ຕ້ອງຖ້າເຖິງມື້ນັດໝາຍ ໃຫ້ຮີບມາໂຮງໝໍ ເພື່ອປິ່ນປົວ ເພື່ອລິດອາການໃຫ້ໂດຍບໍ່ເສຍຄ່າໃຊ້ຈ່າຍ ຫຼື ຢຸດໃຫ້ການປິ່ນປົວໄຂ້ມາລາເຣຍທີ່ໃຊ້ໃນການສຶກສາໃນຄັ້ງນີ້. ແພດອາດລົມກັບພໍ່ແມ່ເພີ່ມເຕີມ ເພື່ອໃຫ້ພໍ່ແມ່ຮູ້ປະຕິບັດ ເມື່ອລູກເຈັບປ່ວຍໃນໄລຍະທີ່ກຳລັງດຳເນີນການສຶກສາ.

<u>ຜູ້ສຳພາດ</u>: ຂ້າພະເຈົ້າໄດ້ກວດສອບ ແລະ ສອບຖາມເດັກ ຊຶ່ງລາວເຂົ້າໃຈ ແລະ ເຂົ້າຮ່ວມການສຶກສາແບບສະໝັກໃຈ. ເຊັນ.....

ເມື່ອທ່ານຕັດສິນໃຈເຂົ້າຮ່ວມໂຄງການ ທ່ານຈະໄດ້ຮັບການປິ່ນປົວຕ່າງໆທີ່ກ່ຽວຂ້ອງກັບພະຍາດໄຂ້ມາລາເຣຍ ຫຼື ພະຍາດໄຂ້ມາລາເຣຍໂດຍທ່ານຈະບໍ່ໄດ້ເສຍຄ່າໃຊ້ຈ່າຍ. ການເຂົ້າຮ່ວມໂຄງການຂອງທ່ານ ຈະຊ່ວຍໃຫ້ເຮົາໝັ້ນໃຈໃນປະສິດທິພາບຂອງຢາປິ່ນປົວພະຍາດໄຂ້ມາລາ-ເຣຍ ແລະນັ້ນຈະເປັນຜົນປະໂຫຍດຕໍ່ຄົນເຈັບອື່ນໆໃນທ້ອງຖິ່ນຂອງທ່ານ.

<u>ຜູ້ສຳພາດ</u>: ຂ້າພະເຈົ້າໄດ້ກວດສອບ ແລະ ສອບຖາມເດັກ ຊຶ່ງລາວເຂົ້າໃຈ ແລະ ເຂົ້າຮ່ວມການສຶກສາແບບສະໝັກໃຈ. ເຊັນ.....

ເນື່ອງຈາກ ບ້ານຂອງເຈົ້າຢູ່ຫ່າງໄກຈາກໂຮງໝໍ, ພວກເຮົາມີປັດໃຈຊ່ວຍເຫຼືອການເດີນທາງໃຫ້ແກ່ພໍ່ແມ່ເລັກນ້ອຍ.

ເຮົາຈະບໍ່ເປີດເຜີຍຂໍ້ມູນສ່ວນຕົວຂອງເດັກໃຫ້ຄົນອື່ນຮູ້. ຂໍ້ມູນຈະເກັບເປັນຄວາມລັບ. ຂໍ້ມູນຂອງເດັກທຸກອັນ ຈະຖືກກຳນົດເປັນລະຫັດ ແຕ່ບໍ່ໄດ້ລະບຸຊື່ຂອງເຈົ້າ ເຊິ່ງຄະນະຜູ້ວິໃຈເທົ່ານັ້ນທີ່ຈະຮູ້ລະຫັດນີ້ ແລະ ລະຫັດຈະຖືກເກັບໄວ້ໃນທີ່ປອດໄພ. ເຮົາຈະໃຫ້ເຈົ້າຮັບຮູ້ຜົນການສຶກສານີ້ກ່ອນທີ່ຈະເຜີຍແຜ່ສູ່ສາທາລະນະ ຈະບໍ່ມີການເຜີຍແຜ່ຂໍ້ມູນທີ່ເປັນສ່ວນຕົວຂອງເຈົ້າ. ຈະມີການນຳສະເໜີຜົນການສຶກສາໃຫ້ໜ່ວຍງານສາທາລະນະສຸກໃນຂັ້ນເມືອງຂອງທ່ານຮັບຮູ້ ແລະ ເຜີຍແຜ່ໃຫ້ຜູ້ທີ່ສົນໃຈອື່ນຮັບຮູ້.

ເມື່ອການສຶກສາສິ້ນສຸດລົງ ພວກເຮົາຈະລົມກັບທ່ານ ແລະ ພໍ່ແມ່ອີກຄັ້ງໜຶ່ງ ແລະ ບອກໃຫ້ທ່ານຮູ້ວ່າຜົນຮັບເປັນແນວໃດ. ຫລັງຈາກນັ້ນ ພວກເຮົາຈະແລກປ່ຽນຂໍ້ມູນກັບນັກວິທະຍາສາດ ແລະ ຄົນອື່ນໆ ກ່ຽວກັບການສຶກສານີ້ ແລະ ຜົນຮັບຂອງມັນ. ພວກເຮົາຈະຂຽນບົດລາຍງານ ເພື່ອແບ່ງປັນກັບຄົນອື່ນ ແລະ ປຸຊຖຸມກັບບຸກຄົນທີ່ມີຄວາມສົນໃຈຕໍ່ການສຶກສານີ້.

ທ່ານສາມາດສອບຖາມໄດ້ທຸກເມື່ອທີ່ຕ້ອງການ ຫຼື ຖາມພະຍາບານກໍ່ໄດ້. ມີງານໄດ້ຈົດເບີໂທລະສັບ ແລະ ທີ່ຢູ່ ທີ່ທ່ານສາມາດພົບພວກເຮົາໄດ້ ຖ້າຢູ່ໄກ້ ທ່ານສາມາດມາພົບເຮົາໄດ້ເລີຍ. ທ່ານສາມາດລົມໃຫ້ຄົນອື່ນຟັງ ກ່ຽວກັບການສຶກສາຄັ້ງນີ້ໄດ້.

ສ່ວນທີ 2. ໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ

ຂ້າພະເຈົ້າໄດ້ຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມໂຄງການສຶກສາປະສິດທິພາບຂອງຢາປິ່ນປົວພະຍາດໄຂ້ມາລາເຣຍ. ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ຜູ້ວິໄຈໄດ້ອ່ານລາຍລະອຽດຂອງໂຄງການໃຫ້ຂ້າພະເຈົ້າຟັງ ພ້ອມໄດ້ສອບຖາມຂໍ້ສົງໄສ ແລະ ໄດ້ຄຳຕອບ ແລະ ອະທິບາຍຈົນເຮັດໃຫ້ຂ້າພະເຈົ້າເຂົ້າໃຈ, ຂ້າພະເຈົ້າຈຶ່ງຍິນດີເຂົ້າຮ່ວມໂຄງການນີ້.

ຊື່ອາສາສະມັກ: _____

ລາຍເຊັນອາສາສະມັກ: _____

ວັນທີ: _____
(ວັນ/ເດືອນ/ປີ)

ຫຼື ຂ້າພະເຈົ້າບໍ່ຕ້ອງການເຂົ້າຮ່ວມການສຶກສານີ້ ແລະ ບໍ່ລົງລາຍເຊັນໃນເອກະສານຍິນຍອມ. ເຊັນ ຫຼື ຂຽນຊື່.....

ລາຍເຊັນພະຍານ: (ຈຳເປັນຕ້ອງມີລາຍເຊັນພະຍານ ຫຼື ພິມລາຍນິ້ວມືຂອງຄົນເຈັບສະເພາະ ຖ້າຄົນເຈັບອ່ານ ຫຼື ຂຽນໜັງສືບໍ່ເປັນ. ພະຍານທີ່ສາມາດອ່ານອອກຂຽນໄດ້ ພະຍາກຈະຕ້ອງເຊັນໃນເອກະສານ. ຖ້າເປັນໄປໄດ້, ພະຍານຄວນປັນບຸກຄົນ ທີ່ຄົນເຈັບຄັດເລືອກເອງ ແລະ ບໍ່ມີສ່ວນກ່ຽວຂ້ອງກັບຄະນະວິໄຈ.)

ຂ້າພະເຈົ້າຂໍເປັນພະຍານວ່າອາສາສະມັກໄດ້ຮັບຮູ້ຂໍ້ມູນໃນໃບຍິນຍອມ ແລະ ໄດ້ສອບຖາມຂໍ້ສົງໃສ ແລະ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ຊື່ພະຍານ: _____

ລາຍເຊັນພະຍານ: _____

ວັນທີ: _____
(ວັນ/ເດືອນ/ປີ)

ພິມລາຍມື ຂອງຜູ້ເຂົ້າຮ່ວມໃນຫ້ອງນີ້

ລາຍເຊັນຜູ້ວິໄຈ:

ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ເປັນພະຍານໃນການອ່ານໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການໃຫ້ຜູ້ປົກຄອງຂອງອາສາສະມັກຟັງ ຊຶ່ງຜູ້ປົກຄອງ ໄດ້ສອບຖາມຂໍ້ສົງໄສ ຂ້າພະເຈົ້າຂໍຢັ້ງຢືນວ່າ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ຊື່ຜູ້ວິໄຈ: _____

ລາຍເຊັນຜູ້ວິໄຈ: _____

ວັນທີ: _____
(ວັນ/ເດືອນ/ປີ)

ອາສາສະມັກຈະໄດ້ຮັບສຳເນົາໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ 1 ສະບັບ _____(ຊື່ຂອງຜູ້ວິໄຈຫຼັກ ຫຼື ຜູ້ຊ່ວຍວິໄຈ)

ໃບຍິນຍອມໃຫ້ກວດການຖືພາ

ຂ້າພະເຂົ້າໄດຮັບການເຊື້ອເຊີນໃຫ້ເຂົ້າຮ່ວມໃນໂຄງການສຶກສາປະສິດທິພາບຂອງຢ່າປັ່ນປົວພະຍາດໄຂ້ມາລາເຣຍ. ຂ້າພະເຈົ້າຖືກຂໍກວດປັດສະວະ ເພື່ອທົດສອບວ່າຂ້າພະເຈົ້າຖືພາ ຫຼື ບໍ່ ໃນມື້ທຳອິດທີເຂົ້າຮ່ວມໂຄງການ ແລະ ມື້ສຸດທ້າຍເມື່ອຕິດຕາມຜົນຄົບໃນມື້ທີ 28 ຫຼື ມື້ທີ່ຂ້າພະເຈົ້າຖອນຕົວຈາກການສຶກສານີ້. ຂ້າພະເຈົ້າຮູ້ວ່າ ຜົນການກວດການຖືພາຂອງຂ້າພະເຈົ້າຈະຖືກເກັບໄວ້ເປັນຄວາມລັບ ແລະ ບໍ່ມີການລະບຸຊື່ຂອງຂ້າພະເຈົ້າ. ຂ້າພະເຈົ້າຮູ້ວ່າຕ້ອງຫຼີກລ້ຽງການຖືພາໃນລະຫວ່າງການສຶກສານີ້ ເນື່ອງຈາກຢາອາດມີຜົນອັນຕະລາຍຕໍ່ລູກຂອງຂ້າພະເຈົ້າ. ຂ້າພະເຈົ້າໄດ້ປຶກສາວິທີຄຸມກຳເນີດແບບຕ່າງໆກັບແພດ ແລະ ໄດ້ຮັບຄຳແນະນຳໃຫ້ໃຊ້ວິທີຄຸມກຳເນີດ. ຂ້າພະເຈົ້າເຂົ້າໃຈດີວ່າ ຖ້າຜົນກວດສະແດງວ່າຖືພາ ຂ້າພະເຈົ້າກໍ່ຈະບໍ່ສາມາດເຂົ້າຮ່ວມໃນການສຶກສານີ້ໄດ້.

ລາຍເຊັນຂອງອາສາສະມັກ:

ຂ້າພະເຈົ້າຍິນຍອມໃຫ້ກວດປັດສະວະ_____(ອັກສອນຕົວທຳອິດຂອງຊື່ອາສາສະມັກ) ຫຼື ຂ້າພະເຈົ້າບໍ່ຍິນຍອມໃຫ້ກວດປັດສະວະ ແລະ ຈະບໍ່ເຊັນຊື່ໃນໃບຍິນຍອມລຸ່ມນີ້ (ອັກສອນຕົວທຳອິດຂອງອາສາສະມັກ)

ຊື່ອາສາສະມັກ: _____

ລາຍເຊັນອາສາສະມັກ: _____

ວັນທີ: _____

(ວັນທີ/ເດືອນ/ປີ)

ລາຍເຊັນພະຍານ (ລາຍເຊັນ ແລະ ພິມລາຍນິ້ວມືອາສາສະມັກຈະໃຊ້ມືອາສາສະມັກບໍ່ຮູ້ໜັງສື ໃນກໍລະນີພະຍານທີ່ສາມາດອ່ານອອກຂຽນໄດ້ ຈະຕ້ອງເຊັນຊື່ເປັນພະຍານ ຖ້າເປັນໄປໄດ້ພະຍານຄວນເປັນບຸກຄົນທີ່ລາວຄັດເລືອກ ແລະ ບໍ່ມີສ່ວນກ່ຽວຂ້ອງກັບຄະນະຜູ້ວິໄຈ)

ຂ້າພະເຈົ້າຂໍເປັນພະຍານວ່າ ໄດ້ຮັບຂໍ້ມູນໃນໃບຍິນຍອມ ມີໂອກາດສອບຖາມຂໍ້ສົງໄສ ແລະ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ມີການບັງຄັບ.

ພິມລາຍນິ້ວມືອາສາສະມັກ

ຊື່ພະຍານ: _____

ລາຍເຊັນພະຍານ: _____

ວັນທີ: _____

(ວັນທີ/ເດືອນ)

ລາຍເຊັນຜູ້ວິໄຈ:

ຂ້າພະເຈົ້າໄດ້ອ່ານ ຫຼື ເປັນພະຍານໃນການອ່ານໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການໃຫ້ຜູ້ປົກຄອງຂອງອາສາສະມັກຟັງ ຊຶ່ງຜູ້ປົກຄອງ ໄດ້ສອບຖາມຂໍ້ສົງໄສ ຂ້າພະເຈົ້າຂໍຢັ້ງຢືນວ່າ ອາສາສະມັກຍິນດີເຂົ້າຮ່ວມໂຄງການໂດຍບໍ່ໄດ້ຖືກບັງຄັບ.

ຊື່ຜູ້ວິໄຈ: _____

ລາຍເຊັນຜູ້ວິໄຈ: _____

ວັນທີ: _____

(ວັນ/ເດືອນ/ປີ)

ອາສາສະມັກຈະໄດ້ຮັບສຳເນົາໃບຍິນຍອມເຂົ້າຮ່ວມໂຄງການ 1 ສະບັບ _____(ຊື່ຂອງຜູ້ວິໄຈຫຼັກ ຫຼື ຜູ້ຊ່ວຍວິໄຈ)