

Peace Corps
Office of Health Services
OMB Control Number 0420-XXXX
Supporting Statement

Section A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Malaria is potentially a deadly disease, but is preventable by taking antimalarials to prevent the disease. Adherence to chemoprophylaxis in long-term travelers like Peace Corps Volunteers (PCVs) is a challenge. In fact, a previous survey of 781 PCVs posted in Africa found that only 73% of PCVs were adherent to malaria chemoprophylaxis, and among those that were non-adherent, 54% cited fear of latent side effects (diseases that might develop years after taking antimalarials for prolonged periods of time) as the reason for nonadherence.^{1,2} There is a dearth of studies on the risk of latent effects of malaria prophylaxis. The multi-year deployment of PCVs to malaria-endemic areas requires them to use malaria prophylaxis for an extended period to time, and thus presents a good opportunity to examine subsequent health outcomes in this group. We propose to compare risk of certain long-term health outcomes among returned PCVs who took malaria chemoprophylaxis to those who did not to describe the outcomes PCVs have had with the use of prolonged chemoprophylaxis. This information would be helpful to Peace Corps to provide some information with which to address fears of latent side effects in order to improve adherence to malaria prophylaxis among their volunteers.

The authorizing law is Section 301 of the Public Health Service Act (42 U.S.C. 241). (Attachment 1). A complete description of the project can be found in the protocol (Attachment 2) attached.

References:

- 1) Landman KZ, Tan KR, Arguin PA, Knowledge, attitudes, and practices regarding antimalarial chemoprophylaxis among US Peace Corps Volunteers – Africa 2013, MMWR 2014; 63: 516-517.
- 2) Landman KZ, Tan KR, Arguin PA, Adherence to malaria prophylaxis among Peace Corps Volunteers in the Africa Region 2013, Travel Medicine and Infectious Diseases 2015; 13: 61-68.

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2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The objective of this information collection is to examine if long-term malaria prophylaxis puts PCVs at higher risk for developing diseases in the future. A matched cohort study is proposed. Returned PCVs who took malaria prophylaxis will be matched to those who did not based on sociodemographic factors (sex, age, smoking, drinking), and risks for certain health diagnoses suspected to be associated with antimalarials will be compared. Confounders such as family history, predisposing health conditions prior to Peace Corps, and other medications will be controlled for in the analysis using multivariable logistic regression. Information from this survey will be compiled and analyzed by the Malaria Branch of the Center for Global Health at the Centers for Disease Control and Prevention (CDC) in conjunction with the Peace Corps Office of Health Services, Epidemiology and Surveillance Unit. More details on the analysis are described in the methods section of the protocol. Findings of the analysis will be used to examine and modify, if needed, current recommendations and policy regarding the use of the different antimalarials for long-term malaria prophylaxis. The results will be shared with the public at a scientific conference and a manuscript which will be submitted to a peer-reviewed journal.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Peace Corp's Office of the Third Goal and Returned Volunteer Services maintains an email distribution list of PCVs who have completed their service. Using this e-mail distribution list, an invitation will be e-mailed to returned PCVs to participate in the survey. This invitation e-mail will contain a link to the survey. The survey will be administered via an online secure, survey platform called Survey Monkey. An online platform for this survey was chosen because answers could be submitted anonymously, and it would allow for skip patterns to be incorporated into the survey to make the survey as efficient as possible for the respondents. Furthermore, because of the anticipated volume of respondents (>15,000), an electronic survey platform such as Survey Monkey can compile the data directly into a dataset, making data management more efficient.

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4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

There is no similar information available. This will be the first time that Peace Corps has instituted such a comprehensive survey to its returned Peace Corps Volunteers about long term malaria chemoprophylaxis and health outcomes.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

This information does not have significant impact on small businesses or other small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

There is currently limited information on latent side effects of the long-term malaria prophylaxis recommended by both the Peace Corps and CDC. While the limited literature on the use of antimalarials suggests that long-term malaria prophylaxis is safe, no data collection of this type has been done. This data collection would be the first of its kind and would add to the scientific body of evidence. Therefore, the consequences of not doing this data collection would be the continuation of policies and recommendations that are assumed to have no long term health risk based on limited evidence.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

There are no special circumstances.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and

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recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The agency's 60-day notice was published in the Federal Register on July 16, 2015, 80 FR 42132. No public comments were received during the 60-day period.

The survey was developed jointly with the Centers for Disease Control and Prevention (CDC). Joint teleconferences have been held to discuss details about collection of the information.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payment, gift, or incentive is provided to survey respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

The respondents are informed that the health information they provide will be done so anonymously. Respondents are provided with a unique identification number that will be sent in an email, which they will use in the survey tool. When these emails are sent, the default of the email program is to put a copy of this email in a "sent items" folder. Once sent, and after the two and four week reminders are sent, these emails in the "sent items" folder containing the unique identifier will be deleted permanently by Peace Corps. Any documentation with the identification number will also be destroyed by Peace Corps. After deletion of this email, and destruction of the documents, there will be no record linking the respondent's name and identification.

The protocol (protocol #6572) for this study has been reviewed by CDC's Human Research Protection Office and was found exempt from institutional review board review under 45 CFR 46.101(b)(2). Documentation of this IRB approval is attached (Attachment 3).

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why

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the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Questions of a sensitive nature are asked solely from a health perspective and the information will be used to analyze the data about long term health consequences from taking malaria prophylaxis. A link in the invitation letter will first show the respondents the consent form for their review. Only those who consent will be allowed to proceed with the survey.

12. Provide estimates of the hour burden of the collection of information. The statement should: * Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

*** If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

*** Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.**

Estimate of hour burden:

Survey responses will be entered electronically onto the Survey Monkey web site, and this is a one-time survey. It is estimated that it will take the average Respondent approximately 25 minutes to complete the Long Term Health Outcomes survey. This estimate was derived from the average time (range was 13-52 minutes) it took eight staff members, most with no medical background, to complete the survey.

The number of RPCVs for 1995-2014 is 65,016. Of that number, Peace Corps has an email address on file for 44,787 (68.9%). By encouraging returned PCVs already on the

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email list to invite additional returned PCV friends, we hope to capture some of the additional 20,229 not on this email list, and any of those that might not have an active email address in Peace Corp's database. To show a range of possible burdens, the total annual hour burden has been estimated using different response rates below.

Response rate	Number of respondents (out of 65,016)	Time to complete survey (mins)	Total annual hour burden (number of respondents x time to complete survey in hours)
25%	16,254	25	6773
50%	32,508	25	13,545
75%	48,762	25	20,318

13. Provide an estimate for the total annual cost burden to respondents or record-keeper's resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

*** The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

*** If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

*** Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government or (4) as part of customary and usual business or private practices.**

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There is no anticipated cost to a respondent resulting from collection of the information on the Long Term Health Outcomes survey.

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

The database manager for this project is responsible for identifying and sending out the email links to the eligible Returned Peace Corps Volunteers. It is estimated it will take the database manager 10 hours to do this is at aFP-4 pay scale. We will use \$46 an hour x 10 hours= \$460. The data will be analyzed by the CDC statistician and epidemiologist, who are at a GS-13 and GS-14 pay scale, respectively. It is estimated the time taken to conduct the analysis will be 80 hours per person. The rate of a GS-13 pay scale is \$48.06/ hour and the rate of a GS-14 pay scale is \$55.41. Therefore, for the CDC statistician, cost will be 80 hours x \$48.06/hr. =\$3844.80. For the CDC epidemiologist, cost will be 80 hours x \$55.41/hr.= \$4432.80. To prepare the report, the services of three Medical Officers at the Peace Corps will be used. The Medical Officers are all at a FP-1 pay scale, being on average \$75/ hour. For preparation and review, we estimate it will take 10 hours x 3 Medical Officers x \$75/hour = \$2250.

The estimated total cost for the dissemination, analysis and preparation of the report for the Long Term Health Outcomes survey is therefore \$10,987.60 (Peace Corps Database analyst + CDC Epidemiologist + CDC Biostatistician + Peace Corps Medical Officers)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

There are no changes to report.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

A matched cohort study will be done. The matched cohort design was chosen to minimize confounding from the matched variables and to maximize power given that our

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sample size will be limited by response rate. Respondents will be matched on sociodemographic and health characteristics that might impact general health status, but are not known to be associated with taking antimalarials: age group, sex, smoking, drinking alcohol, and common diagnoses (diabetes or hypertension). Approximately 60% of the 65,000 returned PCV were given prophylaxis; 45% mefloquine, 26% chloroquine, 20% doxycycline, and 8% malarone. Based on these proportions, we should have the numbers to do a 3:1 match; that is, 3 who took no prophylaxis matched to 1 who took a certain antimalarial drug for prophylaxis. If a 3:1 match is not possible for a certain drug because of the number of respondents available, alternative matching ratios such as 2:1 will be done. Limitations to this study design include poor recall of exposure to antimalarials, dependence of self-reporting for disease outcomes,, missing information on other potential causes of the health endpoints being studied, poor match between cases and controls due to differences in geographic locations and time periods served,, and non-response. We will attempt to assess the extent to which any of these factors introduces bias.

Risk for developing long term disease outcomes (defined as a diagnosis that occurred during and then persists after Peace Corps, or newly diagnosed after Peace Corps) will be compared between those who took specific types of prophylaxis and those who took no prophylaxis. The outcomes of interest are diseases with an onset after leaving Peace Corps requiring ongoing management or medication, and select non-medical outcomes (the need to wear glasses/contacts, and social indicators like marital/partnership status and employment). Select outcomes of interest are grouped into three categories – diseases that are feared to be associated with long-term antimalarial use (but have little evidence in the literature), short-term adverse effects possibly associated with antimalarials (and by extrapolation might be a potential long term adverse outcome), and long-term adverse events. The feared adverse effects were selected based on responses of Peace Corps Volunteers who participated in focus groups that informed the development of the aforementioned survey of Peace Corps Volunteers in the Africa region.^{1,2} Possible short and long term adverse effects to antimalarials have varying degrees of evidence in the literature from rare case reports to adverse events reported in clinical trials. These outcomes are described, and references cited, in the tables below.

Table 1: Adverse effects feared to be associated with prolonged antimalarial use, but with limited to no evidence in the literature^{1,2}

Antimalarial	Feared adverse effects	Corresponding outcome to be examined*
Mefloquine	Psychiatric issues**	Bipolar disorder

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		Dementia
		Obsessive compulsive disorder
	Insomnia	Insomnia
Any antimalarial	“Cancer”	Brain, breast, colon, kidney, liver, lung, skin cancers
		Leukemias
		Lymphoma
	“Kidney problems”	Renal insufficiency
		Renal failure
	Future reproductive issues	Miscarriages

*New diagnosis with onset during and persisting after Peace Corps, or onset after Peace Corps

** Some psychiatric issues that have been reported with mefloquine use are listed in table 2 below.

Table 2: Short term adverse effects* to be extrapolated as possible long term adverse events associated with prolonged antimalarial use

Antimalarial	Short term adverse effects*	Extrapolated outcome to be examined**
Mefloquine	Neuropsychiatric effects ^{3,4}	Schizophrenia
		Depression
		Generalized anxiety disorder
	Lower seizure threshold ³	Seizures
	Cardiac conduction anomalies ⁵	Arrhythmias
		Congestive heart failure
		Myocardial infarction
		Stroke
Chloroquine	Worsening of psoriasis ⁶	New onset psoriasis
Doxycycline	Esophageal ulceration ⁷	Esophageal ulceration
		Esophageal cancer
	Gastrointestinal distress ⁷	Stomach cancer
		Crohn’s or inflammatory bowel disease
		Irritable bowel disease
		Gastro-esophageal reflux

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		Peptic ulcers
	Vaginal yeast infections ⁷	Reccurent vaginal yeast infections
Atovaquone/Proguanil	Elevated liver enzymes ⁸	Cirrhosis
		Fatty liver
		Liver failure
		Liver cancer

*There are varying degrees of evidence for these adverse effects from rare case reports to adverse effects reported in clinical trials, and in some cases these adverse events were reported at treatment, not prophylaxis doses. Also note that some of these adverse effects are noted primarily in individuals with predisposing factors.

**New diagnosis with onset during and persisting after Peace Corps, or onset after Peace Corps

Table 3: Long term adverse effects to be examined*

Antimalarial	Long term adverse effects**
Mefloquine	Vestibular dysfunction ⁹
	Retinopathy ¹⁰
Chloroquine	Retinopathy ¹¹

*The evidence for these adverse effects are primarily from case reports.

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Because these outcomes could also be associated with predisposing conditions and could result from other exposures, factors such as family history, diagnoses prior to and while in Peace Corps, and exposures to other medications will be controlled for in multivariable analysis.

Timeline for project:

Activity	Dates
Office of Management and Budget clearance*	August 2015-April 2016
Study implementation	May or June 2016 (depending on OMB)
Data analysis	July-August 2016

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Report writing and CDC clearance	September-October 2016
Data dissemination	November 2016

Data dissemination will take the form of a report to Peace Corps leadership, an abstract and possible presentation at an international conference, and a manuscript submitted to a peer-reviewed journal.

References:

- 1) Landman KZ, Tan KR, Arguin PA. Knowledge, attitudes, and practices regarding antimalarial chemoprophylaxis among US Peace Corps Volunteers – Africa 2013. *MMWR* 2014; 63: 516-517.
- 2) Landman KZ, Tan KR, Arguin PA. Adherence to malaria prophylaxis among Peace Corps Volunteers in the Africa Region 2013. *Travel Medicine and Infectious Diseases* 2015; 13: 61-68.
- 3) Harinasuta T, Bunnang D, Wernsdorfer WH. A phase II clinical trial of mefloquine in patients with chloroquine-resistant falciparum malaria in Thailand. *Bulletin of the World Health Organization* 1983; 61 (2): 299-305.
- 4) Schlagenhauf P, Tschopp A, Johnson R, Nothdurft HD, et al. Tolerability of malaria chemoprophylaxis in the non-immune travelers to sub-Saharan Africa: multicenter, randomized, double blind, four arm study. *British Medical Journal* 2003; 327.
- 5) Richter J, Burbach G, Hellgren U, Dengler A, Bienzle U. Aberrant atrioventricular conduction triggered by antimalarial prophylaxis with mefloquine. *Lancet*. 1997; 329: 101-102.
- 6) Vine JE, Hymes SR, Warner NB, Cohen PR. Pustular Psoriasis Induced by Hydroxychloroquine: A Case Report and Review of the Literature. *The Journal of Dermatology*. 1996; 23: 357-361.
- 7) Tan KR, Magill AJ, Parise ME, Arguin PM. Doxycycline for Malaria Chemoprophylaxis and Treatment; Report from the CDC Expert Meeting on Malaria Chemoprophylaxis. *American Journal of Tropical Medicine and Hygiene*. 2011; 84(4): 517-531.
- 8) Looareesuwan S, Wilairatana P, Chalermarut K, Rattanapong Y, Canfield C, et al. Efficacy and safety of atovaquone/proguanil compared with mefloquine for treatment of acute plasmodium falciparum malaria in Thailand. *American Journal of Tropical Medicine and Hygiene*. 1999; 60(4); 526-532.
- 9) <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM362232.pdf> (review of cases reported in the FDA Adverse Event Reporting System)
- 10) Walker RA, Colleaux KM, Maculopathy associated with mefloquine (Lariam) therapy for malaria prophylaxis. *Canadian Journal of Ophthalmology*. 2007; 42(1) 125-126.

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- 11) Ferrell D, Retinal toxicity to antimalarial drugs: chloroquine and hydroxychloroquine: a neurophysiologic study, *Clinical Ophthalmology*, 2012: 6 377-383.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable. The Agency is not seeking approval to conceal or omit the expiration date for OMB approval of the information collection.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

The agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-I.

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Section B. Collection of Information Employing Statistical Methods

1. Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection methods to be used. Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

All Returned Peace Corps Volunteers who served between 1995-2014 who are in the *Office of the Third Goal and Returned Volunteer Services* database will receive an email invitation to complete the survey. These volunteers may nominate other Volunteers who may not be on the database (respondent-driven sampling). Currently there are over 65,016 Peace Corps Volunteers in the database for these dates, with 44,787 emails. By encouraging returned PCVs already on the email list to invite additional returned PCV friends, we hope to capture some of the additional 20,229 not on this email list, and any of those that might not have an active email address in Peace Corp's database. Estimated sample size based on various response rates are in the table below.

Overall response rate	Number of respondents (out of 65,016)
25%	16,254
50%	32,508
75%	48,762

2. Describe the procedures for the collection of information including:

- * Statistical methodology for stratification and sample selection,**
- * Estimation procedure,**
- * Degree of accuracy needed for the purpose described in the justification,**
- * Unusual problems requiring specialized sampling procedures, and**
- * Any use of periodic (less frequent than annual) data collection cycles to reduce burden.**

For this one-time survey, we are planning to select all Returned Peace Corps Volunteers who served between 1995-2014 who have emails registered with the Office of the Third Goal and Returned Volunteer Services and who have been nominated by a colleague through respondent-driven sampling. If a conservative power calculation is done using a minimal response rate of 25%, and diseases with varying incidences, it is

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estimated that greater than or equal to 90% power will be achieved for the diseases of interest. An example of this power calculation is below:

Based on Peace Corps records, about 60% of Peace Corps volunteers were prescribed antimalarials for prophylaxis; 45% mefloquine and 26% chloroquine. We therefore anticipate that a 25% response rate will result in 16,250 responses. Of these respondents, 9,750 had been on prophylaxis and 6500 had not. Of those on prophylaxis, 4388 were on mefloquine and 2535 on chloroquine. To do a 3:1 match, 2166 of those who had taken mefloquine will be matched to the 6498 who had taken no prophylaxis, and 2166 of those who had taken chloroquine will be matched to the 6498 who had taken no prophylaxis.

Outcome	Exposed (n)	Unexposed (n)	Estimated disease incidence, unexposed (from literature* †)	Estimated disease risk, exposed (from literature* †)	Estimated RR based on literature	Power
Ocular toxicity	Chloroquine (2166)	6498	0.25/1000 pop	0.5% [0.5-1.0%]	20	92%
Vestibular dysfunction	Mefloquine (2166)	6498	6.5%	8.4%	1.3	90%

*Ferrell D, Retinal toxicity to antimalarial drugs: chloroquine and hydroxychloroquine: a neurophysiologic study, *Clinical Ophthalmology*, 2012: 6 377-383.

Mititelu M, Wong BJ, et al, Progression of hydroxychloroquine toxic effects after drug therapy cessation, *JAMA Ophthalmology*, 2013:131(9):1187-1197.

†Black FO, Pesznecker SC, Vestibular Ototoxicity Clinical Considerations, *Otolaryngologic Clinics of North America*, 1993: 26(5): 719-736.

3. Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

To maximize response rate, a reminder email containing the link to the survey will be sent two and four weeks after the initial email to all invitees. In addition to receiving the email invitation, the survey will be advertised on select Returned Peace Corps Volunteer websites. There are over 130 Returned Peace Corps Volunteer websites across the world.

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4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of test may be submitted for approval separately or in combination with the main collection of information.

An early version of the survey on Survey Monkey was reviewed by five returned Peace Corps Volunteers. Based on their feedback on length of the survey, clarity of the questions, user interface, and user experience, the survey was edited. Skip patterns were also incorporated into the survey to shorten the user experience as much as possible. The final version of the survey on Survey Monkey was tested on eight returned Peace Corps Volunteers to estimate how long it took to complete the survey.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

Names and phone numbers of people analyzing the data:

- a. John Williamson., MS Biostatistician, Division of Parasitic Diseases and Malaria, Centers for Disease Control and Prevention, U.S. Department of Health & Human Services, 404-718-4721
- b. Rennie Ferguson, MPH, Office of Health Services, U.S. Peace Corps, 202-692-2177.