



PRESIDENT'S MALARIA INITIATIVE



# **PMI | Africa IRS (AIRS) Project**

## **Indoor Residual Spraying (IRS 2) Task Order Four**

# **SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT/ADDENDUM: BIOEFFICACY AND RESIDUAL LIFE OF CHLORFENAPYR INSECTICIDE AGAINST ANOPHELES SPP. ACTIVITY – KANJI, NIGER STATE, NIGERIA**

**ADDENDUM 2014**

**Recommended Citation:** Africa Indoor Residual Spraying Program (AIRS). July 2014. *Supplemental Environmental Assessment/Addendum: Bioefficacy and Residual Life of Chlorfenapyr Insecticide Against Anopheles Spp. Activity – Kanji, Niger State, Nigeria. Addendum 2014*. Bethesda, MD. Africa Indoor Residual Spraying Program (AIRS), Abt Associates Inc.

**Contract:** GHN-I-00-09-00013-00

**Task Order:** AID-OAA-TO-11-00039

**Submitted to:** United States Agency for International Development/PMI



Abt Associates Inc. 1 4550 Montgomery Avenue 1 Suite 800 North  
1 Bethesda, Maryland 20814 1 T. 301.347.5000 1 F. 301.913.9061  
1 [www.abtassociates.com](http://www.abtassociates.com)

**SUPPLEMENTAL ENVIRONMENTAL  
ASSESSMENT/ADDENDUM:  
BIOEFFICACY AND RESIDUAL LIFE  
OF CHLORFENAPYR INSECTICIDE  
AGAINST ANOPHELES SPP.  
ACTIVITY – KANJI, NIGER STATE,  
NIGERIA**

**ADDENDUM 2014**

---



# OVERVIEW

---

## SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT: ADDENDUM 2014

### PRESIDENT'S MALARIA INITIATIVE (PMI)

### BIOEFFICACY AND RESIDUAL ACTIVITY OF CHLORFENAPYR INSECTICIDE AGAINST ANOPHELES SPP. ACTIVITY – KANJI, NIGER STATE, NIGERIA

#### PROGRAM/ACTIVITY DATA:

**Contract No.:** GHN-I-00-09-00013-00  
**Task Order No.:** AID-OAA-TO-11-00039  
**Country/ Region:** Nigeria/West Africa  
**Program/Activity Title:** Bioefficacy and Residual Life of Chlorfenapyr Insecticide against Anopheles spp. Activity – Kanji, Niger State, Nigeria  
**Sub-activity:** Supplemental Environmental Assessment Addendum  
**Period of performance:** June 2014 to January 2015  
**Funding amount:** US \$62,260  
**Original submission date:** November 2011 (Indoor Residual Spraying for Malaria Control in Nasarawa State, Nigeria, 2011-2015)  
**Prepared by:** Abt Associates Inc.  
**SEA Amendment (Y/N):** Y Present addendum dated July 2014

#### Other Relevant Environmental Compliance Documentation:

Programmatic Environmental Assessment for Integrated Vector Management in Nigeria, 2006.  
Supplemental Environmental Assessment: Indoor Residual Spraying for Malaria Control in Nasarawa State, Nigeria, 2011-2015, 2011.

#### ENVIRONMENTAL ACTION RECOMMENDED: (Place X where applicable)

Categorical Exclusion: \_\_\_\_\_ Negative Determination: \_\_\_\_\_  
Positive Determination:  \_\_\_\_\_ Deferral: \_\_\_\_\_

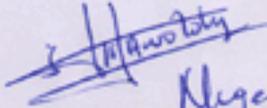
#### ADDITIONAL ELEMENTS: (Place X where applicable)

CONDITIONS:  \_\_\_\_\_

**Conditions:**

- NIMR agrees to follow FAO and WHO standards for the disposal of empty insecticide packaging to a National Environmental Standards and Regulations Enforcement Agency-approved waste management facility.
- AIRS Nigeria and PMI will familiarize the NIMR with the USAID/PMI procedures and protocols for best management practices of indoor residual spraying, and NIMR will follow the mitigation measures included in this SEA amendment.

**ACCEPTANCE OF THE CONDITIONS:**

  
Nigerian Institute of Medical Research  
Receiving Organization

18/08/2014  
Date

# APPROVAL OF ENVIRONMENTAL ACTION – ADDENDUM 2014

The United States Agency for International Development (USAID), Bureau of Global Health has determined that the proposed activity, the bioefficacy and residual life of chlorfenapyr insecticide against *Anopheles* spp. as described in this Supplemental Environmental Assessment (SEA) Addendum dated July 2014, conforms to the requirements established in 22 CFR 216 and the President's Malaria Initiative. The SEA Addendum and Pesticide Evaluation Report and Safe Use Action Plan (PERSUAP) are conducted through a scope of work for technical assistance funding through the Africa Indoor Residual Spray (AIRS) project.

This document does not mandate the execution of the proposed activity, rather it documents environmental assessment, planning and impact analysis executed by the AIRS Nigeria team in preparation for the proposed action. USAID has concluded that the proposed activity, when executed as described in the SEA Addendum and the Programmatic Environmental Assessment, is consistent with USAID's goal of reducing malaria incidence, while minimizing negative impact to environmental and human health. The proposed activity for this SEA Addendum is implementation of entomological surveillance in an environmentally sound manner using the strict protocols and procedures contained in the PMI Best Management Practices (BMP) manual, and observing all precautions and prescriptions in this SEA addendum and PERSUAP. The project has been reviewed and approved by the NIMR IRB and the project conditions have been incorporated into the design implementation.

## RECOMMENDED:

## CLEARANCE:

Michael T. Harvey, Mission Director



Date:

7/31/2014

Allison Belevire, GH/HIDN/MAL Contracting Officer's Representative



Date:

7/31/2014

Elizabeth Fox, GH/HIDN Office Director

Date:

## CONCURRENCE



Rachel Dagovitz, Bureau Environmental Officer, Global Health

Date:

**ADDITIONAL CLEARANCES:**

\_\_\_\_\_  
Nduka Okaro, Mission Environmental Officer, USAID/ Nigeria

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Uwem Inyang, Malaria Program Specialist, USAID PMI/Nigeria

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Jody Stallings, Regional Environmental Advisor, South Africa

\_\_\_\_\_  
Date:

*Brian H*

*7/31/14*

\_\_\_\_\_  
Brian Hirsch, Environmental Officer, Africa Bureau

\_\_\_\_\_  
Date:

# APPROVAL OF ENVIRONMENTAL ACTION – ADDENDUM 2014

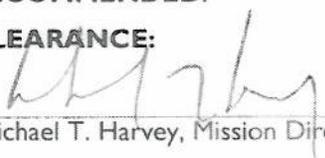
---

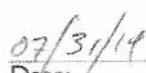
The United States Agency for International Development (USAID), Bureau of Global Health has determined that the proposed activity, the bioefficacy and residual life of chlorfenapyr insecticide against *Anopheles* spp. as described in this Supplemental Environmental Assessment (SEA) Addendum dated July 2014, conforms to the requirements established in 22 CFR 216 and the President's Malaria Initiative. The SEA Addendum and Pesticide Evaluation Report and Safe Use Action Plan (PERSUAP) are conducted through a scope of work for technical assistance funding through the Africa Indoor Residual Spray (AIRS) project.

This document does not mandate the execution of the proposed activity, rather it documents environmental assessment, planning and impact analysis executed by the AIRS Nigeria team in preparation for the proposed action. USAID has concluded that the proposed activity, when executed as described in the SEA Addendum and the Programmatic Environmental Assessment, is consistent with USAID's goal of reducing malaria incidence, while minimizing negative impact to environmental and human health. The proposed activity for this SEA Addendum is implementation of entomological surveillance in an environmentally sound manner using the strict protocols and procedures contained in the PMI Best Management Practices (BMP) manual, and observing all precautions and prescriptions in this SEA addendum and PERSUAP. The project has been reviewed and approved by the NIMR IRB and the project conditions have been incorporated into the design implementation.

## RECOMMENDED:

### CLEARANCE:

  
\_\_\_\_\_  
Michael T. Harvey, Mission Director

  
\_\_\_\_\_  
Date:

\_\_\_\_\_  
Allison Belemvire, GH/HIDN/MAL Contracting Officer's Representative

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Elizabeth Fox, GH/HIDN Office Director

\_\_\_\_\_  
Date:

## CONCURRENCE

\_\_\_\_\_  
Rachel Dagovitz, Bureau Environmental Officer, Global Health

\_\_\_\_\_  
Date:

**ADDITIONAL CLEARANCES:**

Edun Ojofuro  
Nduka Okaro, Mission Environmental Officer, USAID/ Nigeria

07/31/2014  
Date:

email clearance  
Uwem Inyang, Malaria Program Specialist, USAID PMI/Nigeria

08/1/2014  
Date:

Jody Stallings, Regional Environmental Advisor, West Africa

Date:

Brian Hirsch, Environmental Officer, Africa Bureau

Date:



Nduka Okaro &lt;nokaro@usaid.gov&gt;

---

**Re: For Your Action: Nigeria SEA Addendum for Signature**

---

Uwem Inyang <uinyang@usaid.gov>  
To: Nduka Okaro <nokaro@usaid.gov>  
Cc: "Dr Jessica Kafuko (Nigeria/Health)" <jkafuko@usaid.gov>

Fri, Aug 1, 2014 at 8:38 AM

Dear Nduka,

I have gone through the SEA request for the proposed activity to be implemented by Nigerian Institute for Medical Research (NIMR) Lagos at Kainji, Niger State- Nigeria.

Consider this as my Clearance on the activity as I am out of office.

I will work with you to ensure the implementer adheres strictly to Agency policies and Guidelines for this activity.

Regards

On Thu, Jul 31, 2014 at 8:48 AM, Nduka Okaro <nokaro@usaid.gov> wrote:

Hi Uwem,

Greetings from Abuja, hope is well with you. You can clear by email and we will scan along ours to DC.

Thanks

Nduka

On Thu, Jul 31, 2014 at 5:24 AM, Uwem Inyang <uinyang@usaid.gov> wrote:

Dear Nduka,

Good morning and hope you are fine.

The mail below from Allison refers.

The final version of the SEA was attached and there are three signatures from the Mission (up to the Mission Director)

As I am currently out in South Africa attending a training, will like to request if you can sign-off on the signature page first.

Could you also assist to ensure Mission Director signature today.

I am also requesting if Jessica can sign for me or I do have to send an email approval.

Thanks

----- Forwarded message -----

From: **Allison Belemvire** <abelemvire@usaid.gov>

Date: Thu, Jul 31, 2014 at 12:53 AM

Subject: For Your Action: Nigeria SEA Addendum for Signature

To: Uwem Inyang <uinyang@usaid.gov>, Jessica Kafuko <jkafuko@usaid.gov>

Cc: Rachel Dagovitz <rdagovitz@usaid.gov>, Brian Hirsch <BHirsch@usaid.gov>, "jstollings@usaid.gov" <jstollings@usaid.gov>, Nduka Okaro <nokaro@usaid.gov>, Christen Fornadel <cfornadel@usaid.gov>, "Jensen, Elissa (GH/HIDN/ID)" <eljensen@usaid.gov>

Greetings all,

# SUMMARY OF ACTIVITY

---

Given widespread resistance to existing insecticides in most countries where the Presidential Malaria Initiative (PMI) operates, it is imperative to ensure that the program expand the arsenal of insecticides for use in the indoor residual spraying (IRS) program. The pesticide chlorfenapyr, manufactured by BASF Corporation, is an insecticide from the pyrroles class, and presents a possible short-term solution. Chlorfenapyr is not cross-resistant to DDT, pyrethroids, carbamates, or organophosphates.

Chlorfenapyr suspension concentrate (SC) formulation was one of the insecticides approved for use in the USAID Programmatic Environmental Assessment (PEA) of 2012 (see Attachment A). Chlorfenapyr is registered for a similar use by the United States Environmental Protection Agency. Chlorfenapyr SC is currently under review by the World Health Organization Pesticide Evaluation Scheme (WHOPES). The original dossier was submitted to WHOPES in 2011. In October 2013, WHOPES reviewed the documentation, and noted that: (1) in both small- and large-scale trials to date, no spray operators or household inhabitants reported any severe adverse effects from chlorfenapyr, and (2) chlorfenapyr does not pose undue hazards to spray operators or residents of the treated dwellings or to wildlife. The WHOPES then recommended that further evidence be gathered to assess impact on malaria vector populations, and added chlorfenapyr as a footnote to the WHOPES-recommended list of insecticides for IRS (see Attachment B). Given this recommendation, and PMI's urgent need to employ new classes of insecticides, PMI determined that the program would benefit from a study to measure the residual life (i.e., the length of time an insecticide remains effective in killing vectors) of chlorfenapyr.

The small-scale research activity will be conducted by the Nigerian Institute of Medical Research (NIMR) with technical assistance and oversight provided by AIRS Nigeria. Nigeria is one of the only AIRS countries which has test structures (i.e., huts) built in accordance with CDC requirements for entry and exit trap of mosquitoes.

The purpose of the proposed action is to measure the efficacy of chlorfenapyr on key disease vectors. In order to do so, two key activities are proposed:

- A. Assess the insecticidal bioefficacy of key disease vectors to chlorfenapyr in comparison with alpha-cypermethrin and bendiocarb.

In order to assess insecticidal bioefficacy, both susceptible and resistant strains of mosquitoes will be used. All tests will be performed at the NIMR lab. Mosquitoes will be exposed to insecticides in bottle assays and technicians will measure the amount of time needed to knock down and kill the mosquitoes.

- B. Compare the efficacy and residual life of chlorfenapyr applied as an indoor residual spray on relevant substrates with that of bendiocarb and alpha-cypermethrin at WHO recommended doses.

The second activity will be carried out in experimental huts (see Figure 1) located in Monai (Kanji, Niger State, in North Central Nigeria about 500 km from Lagos). Monai is a small isolated fishing village of approximately 400 inhabitants located on the north bank of the River Niger. Mosquito density is high throughout the year, except for the dry season period between November and March, and malaria affects most of the villagers.

Four huts (each with a surface area of approximately 35 square meters) will be used and the insecticide will be applied as follows:

Hut	Insecticide to be applied	Rate (active ingredient/m <sup>2</sup> )
#1	No insecticide (control)	n/a
#2	Chlorfenapyr SC 240 g/L	250 mg/m <sup>2</sup>
#3	Bendiocarb	400 mg/m <sup>2</sup>
#4	Alpha-cypermethrin	30 mg/m <sup>2</sup>

Bendiocarb will serve as a comparison insecticide from the carbamate class of insecticides, and alpha-cypermethrin will serve a comparison insecticide from the pyrethroid class of insecticides; bendiocarb and alpha-cypermethrin are both registered in Nigeria. The walls, windows, ceiling, and door of the huts will be treated with the specified insecticides per the WHOPES recommended dosages using a compression sprayer. One trained spray operator will be used, and it will take one day to complete the spray operation. The spray operator will be trained and supervised directly by an AIRS employee.

To mimic residential life in the huts and attract mosquitoes, volunteers will sleep inside a hut (without a bednet) for up to seven nights on a monthly basis, for up to six months total. Six adult male volunteers (ages 20-30 years) will be recruited for the study among the inhabitants of the village close to the hut site. Sleepers will be rotated randomly among the huts. Sleepers shall enter the hut at night (9 pm) to sleep on the mattresses provided and remain inside until dawn (6 am).

At specified intervals, NIMR will collect data on blood feeding rates, death rates, and entry versus exit rates using window traps. Bioassays will be conducted to determine residual efficacy of all insecticides. In addition, NIMR will record the pH of each wall surface and note the sand, silt and clay content; both have been known to impact the results of bioefficacy.

**FIGURE 1: A STANDARD WHOPES EXPERIMENTAL HUT AT THE NIMR OUTSTATION IN KANJI, NIGERIA**



# PURPOSE OF SEA ADDENDUM

---

Nigeria's current SEA, approved in November 2011, includes language that outlines the due diligence (mitigation) requirements for USAID and its partners in the use of any of the World Health Organization Pesticide Evaluation Scheme (WHOPES) recommended classes of insecticides except organochlorines (DDT) for IRS in Nasarawa State through 2015. This SEA Addendum was prepared in order to provide additional information, necessary mitigation actions, and oversight requirements for an entomological study to be undertaken on behalf of PMI and AIRS Nigeria by the Nigerian Institute of Medical Research (NIMR) on the bioefficacy and residual activity of chlorfenapyr insecticide against anopheles spp. in Kanji (Monai site), Niger State.

Niger State was not covered in the submitted SEA that focused on the region of PMI sponsored IRS activity: Nasarawa State. As such, the geographical scope of Monai site has been described in subsequent sections of the PERSUAP. This Addendum also advises on project requirements for the application by AIRS Nigeria, SEA-prescribed environmental compliance measures and technical standards in using various insecticide classes, including chlorfenapyr. Methodologies will remain as previously stated in the SEA and PERSUAP except where noted below.

## **ADDENDUMS TO SEA (2011) TEXT:**

After Section 2.4.3 Alternative to IRS –Larviciding, insert the following section:

“Section 2.4.4 Bioefficacy and residual life of chlorfenapyr against Anopheles spp.”



**PESTICIDE EVALUATION  
REPORT AND SAFER USE  
ACTION PLAN (PERSUAP) FOR  
BIOEFFICACY AND RESIDUAL  
LIFE OF CHLORFENAPYR  
INSECTICIDE AGAINST  
ANOPHELES SPP. ACTIVITY IN  
KANJI, NIGER STATE, NIGERIA**

July 2014

The authors' views expressed in this report do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

---



# CONTENTS

---

<b>Acronyms</b> .....	<b>v</b>
<b>I. Pesticide Evaluation Report and Safer Use Action Plan (PERSUAP)</b> .....	<b>1</b>
<b>I.1 Pesticide Evaluation Report (PER)</b> .....	<b>1</b>
I.1.1 The United States Environmental Protection Agency's registration status of the requested pesticide .....	1
I.1.2 Basis for selection of the requested pesticides .....	1
I.1.3 Extent to which the proposed pesticide use will be part of an integrated vector management (IVM) program .....	2
I.1.4 Proposed method or methods of application, including availability of appropriate application and safety equipment.....	2
I.1.5 Acute and long-term toxicological hazards associated with the proposed use, and measures available to minimize such hazards .....	3
I.1.6 Effectiveness of the requested pesticide for the proposed use .....	3
I.1.7 Compatibility of the proposed pesticide with target and non target ecosystems.....	3
I.1.8 Conditions under which the pesticide is to be used.....	3
I.1.9 The availability and effectiveness of other pesticides or non-chemical control methods....	3
I.1.10 Ability to regulate or control the distribution, storage, use, and disposal of the requested pesticide .....	4
I.1.11 Provisions made for training of users and applicators.....	4
I.1.12 Provisions made for monitoring the use and effectiveness of the pesticide .....	4
<b>I.2 Safer Use Action Plan (SUAP)</b> .....	<b>5</b>
I.2.1 Pesticide quality assurance .....	5
I.2.2 Pesticide transport.....	5
I.2.3 Warehouse/storage risk management.....	6
I.2.4 Volunteer protection.....	6
I.2.5 Pesticide exposure and treatment.....	7
I.2.6 Accidental warehouse fires .....	7
I.2.7 Fetal exposure (pregnancy testing) .....	7
I.2.8 Spray operator exposure.....	7
I.2.9 Supervisory actions during IRS.....	7
I.2.10 Waste management .....	8
<b>Attachment A</b> .....	<b>9</b>
<b>Attachment B</b> .....	<b>13</b>
<b>Attachment C</b> .....	<b>15</b>



# ACRONYMS

---

<b>BMP</b>	Best Management Practices Manual
<b>CDC</b>	Center for Disease Control
<b>CFR</b>	Code of Federal Regulations
<b>CS</b>	Capsule Suspension
<b>EIA</b>	Environmental Impact Assessment
<b>FAO</b>	Food and Agriculture Organization of the United Nations
<b>IPM</b>	Integrated Pest Management
<b>IRS</b>	Indoor Residual Spraying
<b>ITN</b>	Insecticide-Treated Net
<b>IVM</b>	Integrated Vector Management
<b>LLINs</b>	Long-Lasting Insecticide-treated Nets
<b>MSDS</b>	Material Safety Data Sheet
<b>NESREA</b>	National Environmental Standards and Regulations Enforcement Agency
<b>PERSUAP</b>	Pesticide Evaluation Report and Safe Use Action Plan
<b>PEA</b>	Programmatic Environmental Assessment
<b>PER</b>	Pesticide Evaluation Report
<b>PMI</b>	President's Malaria Initiative
<b>PPE</b>	Personal Protective Equipment
<b>RDT</b>	Rapid Diagnostic Tests
<b>SOP</b>	Spray Operator
<b>UNEP</b>	United Nations Environment Program
<b>USAID</b>	United States Agency for International Development
<b>WHO</b>	World Health Organization
<b>WHOPES</b>	World Health Organization Pesticide Evaluation Scheme



# I. PESTICIDE EVALUATION REPORT AND SAFER USE ACTION PLAN (PERSUAP)

---

The insecticide earmarked for entomological testing is being provided by BASF Corporation and is subject to the United States Code of Federal Regulations, Part 216 (22 CFR 216) that mandates preparation of a PERSUAP. In addition, two WHO-approved insecticides for IRS (bendiocarb and alpha-cypermethrin) will be included in the test to permit comparisons. This PERSUAP addresses two aspects of pesticide use: i) the pesticide evaluation report (PER) which has 12 elements and, ii) the safer use action plan (SUAP) that includes environmental mitigation and monitoring plan.

## I.1 PESTICIDE EVALUATION REPORT (PER)

### I.1.1 THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY'S REGISTRATION STATUS OF THE REQUESTED PESTICIDE

Chlorfenapyr 240 SC is currently registered by the USEPA for some agricultural uses. It has not yet been registered for public health use. Bendiocarb and alpha-cypermethrin are registered for human health uses in Nigeria.

### I.1.2 BASIS FOR SELECTION OF THE REQUESTED PESTICIDES

Chlorfenapyr belongs to the pyrroles class of chemicals, which are not included in the WHOPES-approved classes for IRS. However, it is currently under consideration. This insecticide will be used for the purposes of conducting a bioefficacy and residual activity study to determine whether it is appropriate for IRS.

#### **Primary selection criteria**

- a. The insecticide is registered by the US EPA for agricultural use and is under consideration for public health use.
- b. The insecticide is undergoing Phase III trials for IRS to help manage mosquito resistance.
- c. Chlorfenapyr has a different mode of action and is not cross resistant to DDT, pyrethroid, carbamates or organophosphates in resistant strains of mosquitoes.
- d. The pesticide chlorfenapyr is not yet registered in Nigeria, but NIMR was given permission to receive a shipment of one bottle that will be labelled "for research purpose only". NIMR assumes responsibility for clearing the product through customs, as in other similar research trials.

### 1.1.3 EXTENT TO WHICH THE PROPOSED PESTICIDE USE WILL BE PART OF AN INTEGRATED VECTOR MANAGEMENT (IVM) PROGRAM

IRS is an integral part of IVM for malaria control in Nigeria. IRS, Insecticide Treated Nets, environmental management to reduce available mosquito breeding sites in urban and peri-urban areas, and larval control using larvicides, predators, or growth inhibitors are conducted.

### 1.1.4 PROPOSED METHOD OR METHODS OF APPLICATION, INCLUDING AVAILABILITY OF APPROPRIATE APPLICATION AND SAFETY EQUIPMENT

The proposed method of application is Indoor Residual Spraying (IRS) which involves spraying of a liquid insecticide with long-lasting residual activity on indoor wall surfaces where mosquitoes usually rest before and after taking a blood meal. A lethal dose of the insecticide is absorbed when the mosquito rests on the surface, which results in cell decay thereby killing it. The objective of IRS programs is to reduce the mean life-span of the female mosquito population below the duration required for development of the parasite life phases that occur in the mosquito and, thereby, to substantially reduce the population's ability to sustain malaria transmission.

Spraying of the walls for the study will take place over one day. The pesticide will be applied using pressurized spray equipment that meets WHO guidelines for the pesticide use, by a trained spray operator wearing gloves, overalls, a hard hat with face shield/goggles, a nose/mouth mask, and boots. All necessary PPE for this activity will be supplied by AIRS Nigeria, and its use is supervised and enforced throughout the activity. The spray operator will be trained in and use spray patterns that have proven effective for providing long-lasting toxicity toward the malaria vector mosquito by depositing adequate amount of insecticides.

The spray operator will be supervised by an AIRS Nigeria staff member. The supervisor will ensure that mixing of insecticides and its application on the wall meets the required best practices. They will also ensure that all the spray teams are using the provided PPE appropriately and that these PPE and other IRS materials are properly decontaminated and the waste properly disposed of as per stipulated procedures. To avoid environmental contamination, the supervisor will also ensure proper waste collection, accountability and safe storage. The following guidelines will be applied where necessary:

- Providing extra gloves, boots, face shields, and helmets to mitigate for breakage and loss.
- Replace worn out gloves with new gloves immediately.
- Daily washing of gloves to avoid recontamination.
- Overalls must be changed immediately when a direct spill occurs onto the overalls.
- All working clothes must be removed at the end of each day's operations and a shower or bath taken or cleaning of the exposed parts of the body.
- The spray operator must wash before eating.
- Eating, drinking and smoking during work must be strictly forbidden.
- Overalls must be worn outside of boots, and gloves must be worn outside of overall sleeves, with the last 3 cm folded down.
- The supervisor shall ensure that protective clothing is worn.

### 1.1.5 ACUTE AND LONG-TERM TOXICOLOGICAL HAZARDS ASSOCIATED WITH THE PROPOSED USE, AND MEASURES AVAILABLE TO MINIMIZE SUCH HAZARDS

Chlorfenapyr and the two WHOPES insecticides are toxic to aquatic organisms, birds, and wildlife. When used for indoor residual spraying as instructed, they do not pose undue hazards to the spray operators or residents of the treated dwellings or to wildlife. If inappropriate or malfunctioning equipment is used, or the WHO guidelines and label instructions on operator protection are not followed, exposure may reach the upper range of safe levels.

### 1.1.6 EFFECTIVENESS OF THE REQUESTED PESTICIDE FOR THE PROPOSED USE

Vector (*Anopheles* spp.) susceptibility to chlorfenapyr 240 SC will be assessed during this study. Earlier tests of the insecticide have indicated the absence of cross-resistance in pyrethroid- and DDT-resistant mosquito populations. In addition to susceptibility of the vector to the insecticide, it is also important to evaluate the residual activity of the insecticide and this study will provide information for the assessments. The performance of chlorfenapyr will be compared to two WHOPES insecticides for IRS.

### 1.1.7 COMPATIBILITY OF THE PROPOSED PESTICIDE WITH TARGET AND NON TARGET ECOSYSTEMS

The pesticides are compatible with the target environment in that they dry on these surfaces, and are not released to receptors or the general environment to any great extent. The dried pesticide remains on the sprayed surfaces, and performs as designed, killing vector mosquitos that rest on the walls, and the exposure to non-target organisms and ecosystems is very limited.

The pesticides are incompatible with the non-target ecosystems (humans, animals, and the environment), in that, if they are released to the environment in large quantities, they will have negative effects on land- and water-based flora and fauna. However, the spraying to be conducted in the huts will be designed to ensure that to the maximum extent possible, pesticides are deliberately and carefully applied to the targeted surface of huts, and do not come in contact with humans, animals, or the environment. Spraying is also planned to minimize and responsibly manage the liquid wastes by mixing only the amount required with virtually no leftover, the triple-rinsing of equipment, and washing of PPE. Contaminated solid wastes will be collected and securely stored awaiting transportation for final disposal in a National Environmental Standards and Regulations Enforcement Agency accredited facility that will destroy the pesticide and prevent environmental contamination.

### 1.1.8 CONDITIONS UNDER WHICH THE PESTICIDE IS TO BE USED

The study site (Monai) is situated at Kanji (Niger State), in North Central Nigeria about 500 km from Lagos. It is a small isolated fishing village of about 400 inhabitants located on the north bank of the River Niger. Monai was established after the construction of the Kanji Dam in 1962 at about 20 km from the dam site with perennial mosquitoes breeding sites. During the study, particular attention will be paid to any sensitive areas including water sources, schools, hospitals or subsistence farming gardens.

### 1.1.9 THE AVAILABILITY AND EFFECTIVENESS OF OTHER PESTICIDES OR NON-CHEMICAL CONTROL METHODS

This study is limited to using chlorfenapyr and comparing it to two of the WHOPES recommended pesticides for IRS. The study is for the purpose of evaluating chlorfenapyr as a viable IRS insecticide. Other pesticides or non-chemical control measures will be considered.

### 1.1.10 ABILITY TO REGULATE OR CONTROL THE DISTRIBUTION, STORAGE, USE, AND DISPOSAL OF THE REQUESTED PESTICIDE

Only a limited amount of the insecticides required for spraying the experimental huts will be needed for this study. The insecticides will be stored by NIMR until they are needed for spraying. All facilities used for storage, distribution and transportation of insecticide products should comply with relevant requirements of the Factories Act (Cap 125), National Environmental Standards and Regulations Enforcement Agency (NESREA) Act (2007), and the Nigerian regulations on waste management including disposal of pesticides. The SUAP describe the program approach and strategy for storage, distribution and transportation.

AIRS Nigeria will supervise the spray application and will ensure that the SUAP and other relevant regulations are enforced and implemented. UNHCR environmental regulations should also be adhered to.

### 1.1.11 PROVISIONS MADE FOR TRAINING OF USERS AND APPLICATORS

The effectiveness of the study depends on the use of adequately trained spraying personnel, well-maintained equipment, and competent supervision. USAID has developed guidelines for IRS operations ("*PMI IRS Best Management Practices*"), and WHO provides a training manual, "*Manual for Indoor Residual Spraying*."<sup>1</sup> Other resources include the WHO-UNEP *Manual on Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning*,<sup>2</sup> USAID PMI's IVM PEA (USAID, 2012 Update), as well as this PERSUAP, all of which provide precautions and recommendations that will be employed when spraying the walls of the experimental huts for the study. The IRS BMP manual and the PMI IVM PEA requirements are the primary references and have precedence, but the other documents may be used as a reference. Preparations will include the following:

The spray operator will receive 3 to 5 days of training prior to the spray operation. Priority areas of training will include:

- How to properly mix the pesticide.
- Correct spraying.
- The correct use of protective materials and related safety precautions.
- Support to households on safety issues.
- Personal safety relating to the pesticides used for IRS.
- Environmental safety in relation to pesticides, including management of the empty pesticide sachets, disposal of any leftover pesticide, and proper clean-up equipment and techniques.

### 1.1.12 PROVISIONS MADE FOR MONITORING THE USE AND EFFECTIVENESS OF THE PESTICIDE

The WHO protocol for assessing the effectiveness of the insecticide will be followed. AIRS Nigeria will sign a contract with NIMR which will specify the WHO protocols and concurrence of NIMR to follow them.

---

<sup>1</sup> WHO (2002) *Manual for Indoor Residual Spraying: Application of Residual Sprays for Vector Control* (WHO/CDS/WHOPES/GCDPP/2000.3).

<sup>2</sup> WHO-UNEP *Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning: A Resource Tool*. World Health Organization, Geneva. 332 pages. Document also accessible at: [http://www.who.int/whopes/recommendations/IPCSPesticide\\_ok.pdf](http://www.who.int/whopes/recommendations/IPCSPesticide_ok.pdf)

## 1.2 SAFER USE ACTION PLAN (SUAP)

This section outlines the safer use action plan proposed for the potential adverse impacts outlined above. The primary mitigation measures include training of the spray operator, providing effective supervision and monitoring, and provision of appropriate PPE.

### 1.2.1 PESTICIDE QUALITY ASSURANCE

The insecticide is being procured from the manufacturers who are seeking approval of the insecticide by WHOPES. Pesticide container is labelled for research purposes only.

### 1.2.2 PESTICIDE TRANSPORT

The donated insecticides will be transported by NIMR who will be made aware of all the requirements of this section and will have a documented proof for monitoring purposes. The requirements include:

- Should have enclosed and fully securable truck.
- Driver have received training from NIMR in pesticide safety and the extra caution required on unstable roads, and will be supplied with cell phones and call lists for emergency or spill response.
- Vehicle should be in good condition (have a certification of road worthiness) and capable to transport insecticides to Kanji.
- Written procedures and capacity to handle hazardous materials and emergencies, including accidents. The vehicle should be equipped with PPE for responders, a fire extinguisher and first aid and spill kits.
- Security hired to escort the insecticides and any other insecure place.

In case of insecticide spills during transportation, the following guidelines will be adhered to.

#### **FIGURE 2: EMERGENCY RESPONSE TO INSECTICIDE SPILLS DURING VEHICLE TRANSPORT BY ROAD**

##### IN CASE OF INSECTICIDE SPILLS

- Protective clothing should be donned prior to attempting to clean the spills. A set of PPE should always be carried in the vehicle.
- Control, contain and clean up the spill.
- It is imperative to avoid fire as a result of the accident, and a fire extinguisher should be deployed just in case. The engine should be shut off and smoking in the area strictly prohibited.
- Onlookers and bystanders should be cautioned against approaching the accident site.
- If the crew has come in contact with the pesticides, they should remove contaminated clothing immediately and wash the pesticide off their skin.
- For major spills send for help immediately; drivers should have cell phones and an emergency number for use in such cases.
- People should be kept away and the spill covered with earth, sand, etc.; no attempt should be made to wash away the spill with water or other substances.
- Vehicle that is used for transporting pesticides should be equipped with a bucket of sand, sawdust or soil, a shovel, and fire extinguisher.

At the Kanji site, insecticides will be transported using the project vehicles whose driver will receive additional training on:

- Spray operations
- Handling an accident or emergency (according to FAO standards)
- Handling vehicle contamination (see below)

Drivers will be responsible ensuring that no contamination takes place in the vehicle and that the vehicle is well decontaminated by sponging before being used for other purposes e.g. food transport. Drivers will be provided with overalls, goggles, gloves and nose masks to wear during cleaning of the vehicle. All cloths used in wiping down the interior and bed of the vehicle will be washed at the soak pits.

### 1.2.3 WAREHOUSE/STORAGE RISK MANAGEMENT

The limited quantity of insecticides need for this study will be stored for a short period of time between arrival in Nigeria and time of use. The following procedures will be followed to mitigate the health risks associated with insecticide storage:

- The storage facility will be located away from nearby water courses, domestic wells, markets, schools, hospitals, etc.
- Provide double padlocking and security 24 hours every day.
- The storage facilities will have adequate ventilation and lighting.
- Provide warning/danger signs with skull and cross bones at the door.
- Segregated commodities in the store should be labeled clearly for easy identification.
- MSDS may be laminated and hung where possible and an extra provided for transport vehicles/ motorbikes.
- A fire extinguisher will be available in the storage facilities inside and outside, and all workers will be trained on how to use this device.
- Spill response kit will be provided in all insecticide storage facilities (bucket of sand, shovel and long handle brush).
- A minimum-maximum thermometer should be provided at the store.
- Clean water and soap will be available at all times in the warehouse and other stores for emergency use.
- Trained storekeepers will be hired to manage each store.
- The recommended pesticide stacking position and height of stacks in the warehouse will be used, as provided in the FAO Storage and Stock Control Manual.
- All pesticides will be used and any remnants will be stored under lock and key until the next spray
- All items will be place on pallets and in shelve with proper segregation and labeling.
- The stock control mechanisms will be used to avoid pilferage. NIMR will ensure there is a robust commodity and insecticide distribution and accountability systems.

### 1.2.4 VOLUNTEER PROTECTION

The recruitment of trial volunteers will be led by the village spokesperson from those that have been involved in similar hut studies in the area. They will be informed of the objective of this study and sign

(or through a literate witness, if illiterate) an informed consent form. Each of the volunteers will be given a token (N 1,600) per day to compensate for the period spent with the project and provided with two long lasting insecticidal nets at the end of the project. The volunteers will receive anti-malaria prophylaxis (malarone pills) purchased by BASF Corporation. The NIMR received Institutional Review Board clearance for this activity (see Attachment C, dated June 23, 2014).

### 1.2.5 PESTICIDE EXPOSURE AND TREATMENT

Training of the health workers on insecticide poisoning is highly recommended in the closest health facilities where adverse reactions will be reported and treated. In addition, it is also recommended that eyewash is available.

The spray operator and the supervisor will receive detailed training on the emergency steps to take in case of ingestion or eye or dermal contact with the chemical. Most of the pesticide exposure emergencies will be handled by the qualified and trained health care professionals at a health facility. First aid kits will be provided to the storage facilities as well as made available at the site for use in case of an emergency.

### 1.2.6 ACCIDENTAL WAREHOUSE FIRES

Human inhalation of toxic fumes in the event of a storehouse fire is also an unavoidable risk. The risk can be minimized, however, by following BMPs for storage, including prohibiting lighted materials in the warehouse and in the vicinity of pesticides and providing proper ventilation. Fire extinguishers should be provided at the storehouses.

### 1.2.7 FETAL EXPOSURE (PREGNANCY TESTING)

If the spray operator is a woman of childbearing age, then she will be tested for pregnancy before being engaged into the spray operation.

### 1.2.8 SPRAY OPERATOR EXPOSURE

The spray operator will be trained on recognition of the symptoms of poisoning, incident response elevation protocol. The spray operator will be provided with the following safety equipment, in accordance with WHO and FAO as well as PMI BMP specifications. If spraying takes longer than a day to complete, the spray operator's respirator will be replaced every day:

- Broad-brimmed hat/helmet
- Face shield or goggles (face shield preferable)
- Respirators-disposable and replaced on a daily basis
- A set of cotton overalls
- Nitrile rubber, neoprene, PVC or butyl rubber gloves, without inside lining, long enough to cover forearm and replaced if torn or if wear and tear is noticed
- Rubber boots

The spray operator will be asked to report any adverse reactions to NIMR as a form of best practice, and action taken: i.e., immediate treatment following guidance given, or referral to health facilities for further treatment.

### 1.2.9 SUPERVISORY ACTIONS DURING IRS

Since only one spray operator will be required to spray the huts, AIRS Nigeria will provide one supervisor. The role of the supervisor will be clearly stipulated as follows:

- Observe spray operator during mixing and ensure quality spraying.
- Ensure sprayer and PPE clean-up at the end of spraying.
- Ensure accurate reporting for the spray data.

#### 1.2.10 WASTE MANAGEMENT

All wastes will be disposed according to PMI's BMP manual. Liquid wastes from PPE decontamination, storage facilities cleaning, spray pump progressive rinsing and vehicle decontamination will be disposed of in a pit latrine which is located away from the residential areas and underground water sources. This will allow for dilution and eventual biodegradation.

All contaminated and non-contaminated solid wastes in form of empty sachets, gloves, nose masks, packaging materials will be collected and securely stored in the warehouse. They will then be securely packaged, quantified and transported for safe disposal by a National Environmental Standards and Regulations Agency-accredited facility that meets the PMI BMP requirements.

# ATTACHMENT A

The pesticides listed below are appropriate for use in the IRS program (INTEGRATED VECTOR MANAGEMENT PROGRAMS FOR MALARIA CONTROL, Sept 2012)

Pesticide	Properties	Toxicology	PEA findings
Alpha-cypermethrin	Pyrethroid	Low risk to humans, skin and eyes irritant; can bioaccumulate in aquatic organisms; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	<i>Low risk</i>
Bendiocarb	Carbamate	Some risk to humans; reversible cholinesterase inhibition; moderately toxic in mammals; exposure to treated surfaces there were risks of concern for children and adults; degrades rapidly in water and has low persistence in soil; moderately toxic to birds and fish, and toxic to bees.	<i>Low risk</i>
Bifenthrin	Pyrethroid	Used in agriculture: skin and eye irritation; biodegrades readily; moderately toxic to birds; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	<i>Low risk</i>
Cyfluthrin	Pyrethroid	No long term problems to humans, skin and eye irritation; no evidence of carcinogenic potential of cyfluthrin has been reported in animals; can bioaccumulate in aquatic organisms; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	<i>Low risk</i> Found in breast milk
DDT	Organo-chlorine	Past use in agriculture; high persistence; concern for prenatal exposure; persistent in soil, shorter life in warm, wet tropics; bioaccumulates in marine life; synergisms between DDT and OP may produce greater toxicity to the nervous system; nontoxic to birds, but impacts reproduction; highly toxic to aquatic species; non-toxic to bees.	<i>High Risk</i> In humans, oral exposure is thought to be most significant; concern with DDT in breast milk; high risk of cancer during preparation and spraying for high end exposure estimate (with 2 year exposure); may need extra PPE protection; high noncancer risks during preparation and spraying due to dermal exposure, recommend use of PPE (may need extra PPE protection); low quantities can contaminate groundwater; avoid disposal on land with sandy soil and shallow ground

<b>Pesticide</b>	<b>Properties</b>	<b>Toxicology</b>	<b>PEA findings</b>
			water; unacceptable acute exposures from food sprayed during IRS; minimum cancer risk from ingestion of chickens exposed to DDT; studies have found that DDT is migrating into the environment from sprayed homes – <i>note: recommend appropriate packaging (leak proof) and BMP handling of all DDT, only for indoor use (not eaves / outside of homes)</i>
Deltamethrin	Powerful broad-spectrum pyrethroid	Low risk to humans; skin and eye irritation; moderate toxicity to mammals; degrades in soil and plants; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	<i>Low risk</i>  Found in breast milk
Etofenprox	Pyrethroid	Low risk for acute toxicity in humans; not a cholinesterase inhibitor; degrades in sunlight; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	<i>Moderate Risk</i> Low cancer risk during preparation and spraying; low quantities can contaminate groundwater; avoid disposal on land with sandy soil and shallow ground water.
Fenitrothion	Organo-phosphate	Overstimulation of the nervous system due to cholinesterase inhibition; evidence of noncarcinogenicity for humans; broad-spectrum insecticide uses have been cancelled in the United States, it is now only registered for use in ant and roach baits with child-resistant packaging; breaks down in soils; somewhat toxic to birds and fish, highly toxic to aquatic invertebrates; highly toxic to bees.	<i>Moderate Risk</i> High noncancer risk during preparation and spraying; wearing PPE reduces risk to reasonable level; low quantities can contaminate groundwater; avoid disposal on land with sandy soil and shallow ground water; unacceptable acute exposures from food sprayed during IRS.
Lambda-cyhalothrin	Pyrethroid	Used for agriculture and animal health; degrades rapidly by sunlight, and is slightly persistent; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	<i>Low risk</i>
Malathion	Broad-spectrum organo-phosphate	Used for agriculture and animal health; causes neurological effects by inhibiting cholinesterase in the blood and brain; no longer permitted in the United States for any indoor uses; degrades rapidly; moderately toxic to birds; wide range of toxicity to fish; highly toxic to bees.	<i>Low Risk</i> Unacceptable acute exposures from food sprayed during IRS
Pirimiphos-methyl	Fast-acting, broad-spectrum, non-cumulative organo-	Acts by inhibiting cholinesterase activity; low mammalian toxicity; moderately toxic to freshwater fish and invertebrates; highly toxic to estuarine invertebrates.	<i>High Risk</i> High noncancer risk during preparation and spraying from dermal exposure, recommend use of PPE (observable

Pesticide	Properties	Toxicology	PEA findings
	phosphate		adverse effects); may need extra PPE protection; risk of dermal exposure from residue on walls; unacceptable acute exposures from food sprayed during IRS; avoid disposal on land with sandy soil and shallow ground water.
Propoxur	Broad-spectrum carbamate	Reversible cholinesterase inhibition; moderate toxicity in mammals; mobile in the soil; potential to leach into groundwater; degrades rapidly in water; highly toxic to birds, moderately toxic to fish, highly toxic to bees.	<i>Moderate Risk</i> Low cancer risk during preparation and spraying; low quantities can contaminate groundwater, avoid disposal on land with sandy soil and shallow ground water.
Chlorfenapyr (new)	Pyrroles class	Good for resistance to OPs, carbamates and pyrethroids; degrades slowly in soil, sediment and water; toxic to birds, fish and highly toxic to bees.	<i>Moderate Risk</i> High noncancer risk during preparation and spraying, wearing PPE reduces risk to reasonable level.



# ATTACHMENT B

World Health Organization Recommended Insecticides for IRS

Updated: 25 October 2013

## WHO recommended insecticides for indoor residual spraying against malaria vectors

<b>Insecticide compounds and formulations<sup>1</sup></b>	<b>Class group<sup>2</sup></b>	<b>Dosage (g a.i./m<sup>2</sup>)</b>	<b>Mode of action</b>	<b>Duration of effective action (months)</b>
<i>DDT WP</i>	OC	1-2	contact	>6
<i>Malathion WP</i>	OP	2	contact	2–3
<i>Fenitrothion WP</i>	OP	2	contact & airborne	3–6
<i>Pirimiphos-methyl WP &amp; EC</i>	OP	1-2	contact & airborne	2–3
<i>Pirimiphos-methyl CS</i>	OP	1	contact & airborne	4–6
<i>Bendiocarb WP</i>	C	0.1–0.4	contact & airborne	2–6
<i>Propoxur WP</i>	C	1–2	contact & airborne	3–6
<i>Alpha-cypermethrin WP &amp; SC</i>	PY	0.02–0.03	contact	4–6
<i>Bifenthrin WP</i>	PY	0.025–0.05	contact	3–6
<i>Cyfluthrin WP</i>	PY	0.02–0.05	contact	3–6
<i>Deltamethrin SC-PE</i>	PY	0.02–0.025	contact	6
<i>Deltamethrin WP, WG</i>	PY	0.02–0.025	contact	3–6
<i>Etofenprox WP</i>	PY	0.1–0.3	contact	3–6
<i>Lambda-cyhalothrin WP, CS</i>	PY	0.02–0.03	contact	3–6

**Chlorfenapyr 240 SC:** The current assessment of Chlorfenapyr SC (class group: pyrrole) is available in the report of the 16<sup>th</sup> WHOPES Working Group meeting, 22–30 July 2013 at: <http://www.who.int/whopes/recommendations/en/>

**Note:** WHO recommendations on the use of pesticides in public health are valid ONLY if linked to WHO specifications for their quality control. WHO specifications for public health pesticides are available on the WHO homepage on the Internet at <http://www.who.int/whopes/quality/en/>.

<sup>1</sup> CS = capsule suspension; EC = emulsifiable concentrate; SC = suspension concentrate; SC-PE = polymer enhanced suspension concentrate; WG = water dispersible granule; WP = wettable powder.

<sup>2</sup> OC = organochlorines; OP = organophosphates; C = carbamates; PY = pyrethroids.



# ATTACHMENT C

Institutional Review Board approval to conduct efficacy trial

 **INSTITUTIONAL REVIEW BOARD**   
**NIGERIAN INSTITUTE OF MEDICAL RESEARCH**  
6, Edmond Crescent Off Murtala Muhammed Way, P.M.B. 2013 Yaba, Lagos.  
Tel: 01-4823123, 01-7744723, 08050254484, 08033460947 Fax: 01-4823123, 234-1-3425171  
E-mail: nimr\_urb@yahoo.com Website: www.nimr-nig.org  
Secretariat: Room 207, Biochemistry Division, Research Block, NIMR

23<sup>rd</sup> June, 2014

**PROJECT TITLE:** FIELD AND EXPERIMENTAL HUT EVALUATION OF  
BIO-EFFICACY AND RESIDUAL EFFICACY OF  
CHLORFENAPYR INSECTICIDE AGAINST  
ANOPHELES SPECIES

**PROJECT No:** IRB/14/262

**APPROVAL LETTER**

The above named proposal has been adequately reviewed; the protocol and safety guidelines satisfy the conditions of NIMR-IRB, policies regarding experiments that use human subjects.

Therefore the study under its reviewed state is hereby approved by Institutional Review Board, NIMR.

**PROF. F. E. OKONOFUA**  
Name of IRB Chairman

**MRS. O. A. NWOGBE**  
Name of IRB Secretary

  
Signature of IRB Chairman & Date  
Signature of IRB Secretary & Date 23/6/14

**This approval is given with the investigator's Declaration as stated below;  
By signing below I agree/certify that:**

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.
2. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
  - I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.

- I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
3. I will ensure that all co-investigators and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping; and (f) the current IRB approval status of the research study.
  4. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.
  5. I will submit the research study in a timely manner for IRB renewal approval.
  6. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his /her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).
  7. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.
  8. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
  9. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.
  10. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.
  11. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
  12. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines

**DR. T. S. AWOLOLA**  
Principal Investigator's Name

*[Handwritten Signature]*  
Principal Investigator's Signature and Date  
28/06/2014

