REQUEST FOR CEO APPROVAL

PROJECT TYPE: Medium-sized Project
TYPE OF TRUST FUND:GEF Trust Fund

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PART I: PROJECT INFORMATION

Project Title: Microbial Larviciding, Human Health, and the Control of Malaria			
Country(ies):	United Republic of Tanzania	GEF Project ID:[1]	5705
GEF Agency(ies):	UNEP (select) (select)	GEF Agency Project ID:	
Other Executing Partner(s):	Kilimanjaro Christian Medical College (KCMC)	Submission Date:	22 September 2015
GEF Focal Area (s):	Persistent Organic Pollutants	Project Duration(Months)	36
Name of Parent Program (if applicable): ➢ For SFM/REDD+ ☐ ➢ For SGP ☐ ➢ For PPP ☐		Project Agency Fee ($):	92,625

A. FOCAL AREA STRATEGY FRAMEWORK[2]

Focal Area Objectives	Expected FA Outcomes	Expected FA Outputs	Trust Fund	Grant Amount ($)	Cofinancing ($)
(select) CHEM-1	Outcome 1.1 "Production and use of controlled POPs chemicals phased out"	Output 1.1.2 Countries receiving GEF support to pilot "new POPs" reduction activities. Output 1.2.1 Countries receiving GEF support for environmentally sound management of DDT.	GEF TF	975,000	3,926,083
(select) (select)			(select)		
(select) (select)			(select)		
(select) (select)			(select)		
(select) (select)			(select)		
		Total project costs		975,000	3,926,083

B. PROJECT FRAMEWORK

[1] Project ID number will be assigned by GEFSEC.
[2] Refer to the Focal Area Results Framework and LDCF/SCCF Framework when completing Table A.

Project Objective: Integration of community-based microbial larviciding into the national integrated vector management (IVM) strategy						
Project Component	**Grant Type**	**Expected Outcomes**	**Expected Outputs**	**Trust Fund**	**Grant Amount ($)**	**Confirmed Cofinancing ($)**
Integration of community-based microbial larviciding into the national integrated vector management (IVM) strategy	TA	1. Creation of new knowledge about the cost-effectiveness and practicality of farmer application of microbial larviciding as an alternative to DDT and other chemical approaches to malaria control	1.1 Proof of concept and experimental plot studies designed and implemented 1.2 Field experiments designed and implemented 1.3 Socio-economic studies on local perceptions and attitudes towards larviciding and farmer application conducted 1.4 Disseminating of lessons learned and integrated into policy guidance	GEF TF	910,500	3,642,000
	(select)			(select)		
	(select)			(select)		
	(select)			(select)		
	(select)			(select)		
	(select)			(select)		
	(select)			(select)		
	(select)			(select)		
			Subtotal		910,500	3,642,000
			Project management Cost (PMC)[3]	GEF TF	64,500	284,083
			Total project costs		975,000	3,926,083

[3] PMC should be charged proportionately to focal areas based on focal area project grant amount in Table D below.

C. SOURCES OF CONFIRMED COFINANCING FOR THE PROJECT BY SOURCE AND BY NAME ($)

Please include letters confirming cofinancing for the projeSct with this form

Sources of Co-financing	Name of Co-financier (source)	Type of Cofinancing	Cofinancing Amount ($)
Private Sector	IVCC grants to KCMC	Cash	668,126
Private Sector	Duke University	In-kind	603,007
Private Sector	Biovision foundation grant to ICIPE	Cash	462,500
Others	University of Michigan	In-kind	229,500
Others	Lower Moshi development schemes	In-kind	1,962,950
(select)		(select)	
(select)		(select)	
(select)		(select)	
(select)		(select)	
Total Co-financing			3,926,083

D. TRUST FUND RESOURCES REQUESTED BY AGENCY, FOCAL AREA AND COUNTRY[1]

GEF Agency	Type of Trust Fund	Focal Area	Country Name/ Global	(in $)		
				Grant Amount (a)	Agency Fee (b)[2]	Total c=a+b
UNEP	GEF TF	Persistent Organic Pollutants	United Republic of Tanzania	975,000	92,625	1,067,625
(select)	(select)	(select)				0
(select)	(select)	(select)				0
Total Grant Resources				975,000	92,625	1,067,625

[1] In case of a single focal area, single country, single GEF Agency project, and single trust fund project, no need to provide information for this table. PMC amount from Table B should be included proportionately to the focal area amount in this table.
[2] Indicate fees related to this project.

F. CONSULTANTS WORKING FOR TECHNICAL ASSISTANCE COMPONENTS:

Component	Grant Amount ($)	Cofinancing ($)	Project Total ($)
International Consultants	468,000	1,295,007	1,763,007
National/Local Consultants	96,500	0	96,500

G. DOES THE PROJECT INCLUDE A "NON-GRANT" INSTRUMENT? No

(If non-grant instruments are used, provide in Annex D an indicative calendar of expected reflows to your Agency and to the GEF/LDCF/SCCF/NPIF Trust Fund).

PART II: PROJECT JUSTIFICATION

A. DESCRIBE ANY CHANGES IN ALIGNMENT WITH THE PROJECT DESIGN OF THE ORIGINAL PIF[4]

The project will achieve the same results as approved in the PIF. The project framework and structure described herein is, however, different to the original PIF. It is should be noted that the changes are presentational and have been initiated in order to better group the related Outputs and Activities and so make project implementation and reporting easier and more coherent. The revised structure has been developed based on consultation with the UNEP Quality Assurance Section (QAS) in Nairobi and is compliant with UNEP internal results based management (RBM) practices. The related project logical framework / results matrix has been developed based on the current guidance from QAS on the need for Outcome and Output descriptions which can have the necessary level of detail and also ensure that indicators are set at a level where impacts and results can be clearly reported. The changes to the structure related to this specific project are:

The original PIF contained 5 Components with multiple Outcomes which, for a project of this size, is overly complex. The review of the PIF has allowed for the Components to be collapsed to a single area of focus with one primary behavioral change (Outcome) which is the uptake of larviciding as an alternative to chemical pesticides for malaria vector control. Areas previously described as Outcomes are now restructured to detail the appropriate Output with the original outputs now better classified as activities in the work plan for implementation. No activities envisaged at the PIF stage have been removed and the cost implications of this reformatting is zero.

A.1 National strategies and plans or reports and assessments under relevant conventions, if applicable, i.e. NAPAS, NAPs, NBSAPs, national communications, TNAs, NCSA, NIPs, PRSPs, NPFE, Biennial Update Reports, etc.

The United Nations Development Assistance Framework (UNDAF) for Tanzania for the period of 2007 through mid-2011 promoted more progressive partnerships owing in part to the commitment to increasing national ownership and capacity building for improved policy-making. The UNDAF pursued 6 main themes, among them gender, children and the environment. Malaria morbidity and mortality rates are higher among pregnant women and children, who are more vulnerable to the effects of the disease. The UNDAF noted that the health and wellbeing of these populations would be improved by the development of additional sustainable and effective alternatives to malaria control. The project stands to contribute to the development and implementation of an environmentally friendly intervention within the broader approach of vector control through environmental management and IVM.

The United Nations Development Assistance Plan (UNDAP) 2011 – 2015 builds on the foundations laid by the UNDAF and again focuses on clusters related to Economic Growth and Poverty Reduction (Cluster 1) and Quality of Life and Social Well-being (Cluster 2). The Environmental and Health linkages achieved under this project therefore fit into these two clusters. Both clusters focus on community level action to ensure maximum impact at local level. This project adopts this approach and so is consistent with the overall UNDAP strategy.

The project is consistent with national strategies in Tanzania with regards to reduction of the malaria burden and DDT use. Tanzania ratified the Stockholm Convention on Persistent Organic Pollutants in 2004, and produced its National Implementation Plan (NIP) in December of 2005, to cover a fifteen-year

[4] For questions A.1 –A.7 in Part II, if there are no changes since PIF and if not specifically requested in the review sheet at PIF stage, then no need to respond, please enter "NA" after the respective question.

period that began in 2006. Within the NIP, the Action Plan for DDT has as its main goal the elimination of the release of DDT into the environment. While DDT is not currently used in crop or public health applications, the NIP expressed the intention of the Ministry of Health to use DDT for indoor residual spraying (IRS) while simultaneously calling for more support for research and dissemination of DDT alternatives. This project was conceived and developed to address this call for more research with an aim to mitigate the intended re-introduction of DDT as stated in the NIP.

DDT has been used recently in other African countries as IRS for malaria vector control and the pressures to incorporate DDT into malaria vector control policy will remain unless information on and access to effective, efficient, sustainable non-DDT alternatives is readily available. Developing safe and effective alternatives to DDT will prevent Tanzania and other countries from restarting their use of DDT. Currently there is a great deal of concern in Tanzania about the emergence of resistance to insecticides currently used for IRS. Larviciding is one of the alternative vector control methods that shows promise but has not been used extensively in rural areas. While the "Strategy and Action Plan Elements of the National Implementation Plan" (Section 4 of Tanzania's NIP) states that one of its overall objectives is to promote the research and development of alternatives to DDT (especially IVM strategies), it also identifies as a major constraint the lack of resources for assessing feasibility of alternatives (e.g., in terms of effectiveness, cost, and acceptability). Thus, the project would address both a key objective and a major constraint to the action plan set forth in Tanzania's NIP. NIMR is a partner in the proposed project, consistent with the NIP Action Plan on DDT, which indicates NIMR as having lead responsibility for promoting use of alternatives to DDT. More generally, the NIP notes challenges to managing POPs according to the Stockholm Convention include inadequate policy and insufficient institutional capacity (i.e., human resources, technical infrastructure), both of which are issues the project seeks to address.

The current National Malaria Strategic Plan 2014–2020 for Tanzania highlights integrated malaria vector control as one of five components central to the Plan, and reaffirms that "malaria vector control remains a top priority for the country." Larviciding receives mention as part of the national malaria vector control strategy, but the emphasis is on implementing larviciding efforts in urban areas. This project would respond to a need to further explore, contextualize and define the place of larviciding in the complicated array of malaria control methods by providing key stakeholders and decision-makers more and clearer information on various parameters of its use, including its impact, cost-effectiveness, necessary coverage levels, potential synergistic effects, and sustainability, with an emphases on the potential of novel rural community-supported application methods.

Policymakers have underscored their receptiveness to novel approaches, such as this project's, as the Plan states that "new innovations especially those that address the emerging threat of insecticide resistance and preserving the effectiveness of modern malaria vector control will be considered as they become available". A specific objective of the Plan's integrated malaria vector control strategy is to "provide a strategic framework for coordination and continuous assessment for the implementation of evidence-based IVM interventions, so that at least two new innovations for malaria control are adopted in Tanzania by 2020". The project reflects these priorities identified in the National Malaria Strategic Plan as it seeks to develop and build the evidence-base for an innovative non-chemical vector control method and integrate it into an existing decision-support framework already familiar to key in-country malaria control stakeholders.

The issue of emerging pyrethroid insecticide resistance in Tanzania is highlighted in the current (FY2015) President's Malaria Initiative (PMI) Malaria Operational Plan for Tanzania, developed in consultation with the Tanzania National Malaria Control Program (NMCP). The National Institute for Medical Research (NIMR) currently monitors insecticide resistance in 22 sites; in 2013, 18 sites were evaluated and resistance was identified to permethrin in 10 of these sites, resistance to lambdacyhalothrin in 13 of the sites, and resistance to deltamethrin in 6 of the sites. Further developing complementary IVM strategies, and non-chemical alternatives to DDT and other pesticides in particular, could aid in addressing this resistance issue. Larviciding in particular has been promoted, including in the current

National Malaria Strategic Plan, as a strategy that might support insecticide resistance management since it may aid in decreasing selection pressure. The development of non-chemical alternatives is also aligned with key aspects of COP5 Decision SC-5/6 on DDT and directly responds to the mandate of The Global Alliance for the Development and Deployment of Products, Methods, and Strategies as Alternatives to DDT for Disease Vector Control.

Beyond specific national malaria control strategies, the proposed project is in alignment with the national priorities and approaches to development as more generally outlined in key national policy documents. In particular, the community-supported aspect of the proposed project is in line with the Tanzania National Development Vision 2025, which includes specific commitments to "encouraging community participation" and "empowering…community members in all health related issues". In addition, the project seeks to make a contribution to a key element of the National Strategy for Growth and Reduction of Poverty, namely "strengthening government's and national implementation capacity" (specifically with regards to integrating community-based microbial larviciding into the national IVM strategy).

A.2. GEF focal area and/or fund(s) strategies, eligibility criteria and priorities.

The project is oriented towards the effective implementation of non-chemical DDT alternatives consistent with the objectives of the Stockholm Convention on Persistent Organic Pollutants (POPs). In particular, the project would contribute to the CHEM-1 focal area objective through the expected outcomes of phasing out of production and use of controlled POPs chemicals, specifically DDT and reducing POPs releases into the environment (GEF V, Strategy Objective 1). The proposed project addresses key aspects of COP5 Decision SC-5/6 on DDT, especially with regards to the need for alternatives to DDT for disease vector control that are safe, effective, affordable, and locally appropriate. This commitment to developing non-chemical alternatives has been sustained, as evidenced in the road map for the development of alternatives to DDT which was commissioned during COP6 and presented during the proceedings of COP7. The proposed project would contribute to key elements of implementing the road map for the development of alternatives to DDT (as outlined in Table 11, UNEP/POPS/COP.7/INF/6), specifically its intent to "strengthen country and local capacities to…assess and deploy alternatives" (road map element 2.2) and "share experiences and upscaling the application of non-chemical alternatives" (road map element 2.4). The proposed project also directly responds to the mandate and thematic groups of The Global Alliance for the Development and Deployment of Products, Methods, and Strategies as Alternatives to DDT for Disease Vector Control, particularly with regards to building an evidence base to inform policy formulation on non-chemical alternatives to DDT.

The project will link with regional efforts by WHO, UNEP, and FAO to promote the adoption of integrated vector management (IVM).

A.3 The GEF Agency's comparative advantage:

The GEF Implementing Agency UNEP will be the implementing agency of this project. UNEP has supported a range of relevant and informative FSPs, MSPs, and other activities that have strengthened the focus on alternatives to DDT through the Demonstrating and Scaling-up of Sustainable Alternatives to DDT in Vector Management Global Program (Global DSSA Program). This includes the MDAST project, and various larger regional projects in the same AFRO zone as the current project, which have explicit linkages to outcomes, partnerships, and stakeholders as in the proposed project.

A.4. The baseline project and the problem that it seeks to address:

Baseline:

The use of DDT in indoor residual spraying (IRS) programs is perhaps the most controversial strategy for battling malaria. Spraying indoor building surfaces with DDT has been highly effective in suppressing malaria transmission in many developing countries, but DDT can also be toxic to wildlife and potentially

harmful to humans. However, in those malaria endemic countries where the local vector species remains susceptible to this insecticide, DDT often continues to be the cheapest option for control. Under the Stockholm Convention on Persistent Organic Pollutants (POPs), countries are authorized to elect further use of DDT for malaria vector control when locally safe, effective, and affordable alternatives are not available; countries are obliged to develop and implement action plans to reduce reliance on DDT. While DDT is not currently being used in Tanzania, WHO-AFRO reported that there were 8 African countries using a total of 337.9 tonnes of DDT in 2014 for disease vector control. Tanzania's National Implementation Plan (NIP) for the Stockholm Convention expressed the intention of the Ministry of Health to use DDT for IRS, and Tanzania is one of the signatories of the Abuja Convention (2013) where African countries agreed to increase the use of DDT in malaria control. The best way to reduce and eventually eliminate the use of DDT for disease vector control is to develop and implement alternative methods which are safer, effective, contextually appropriate, and sustainable. This strategy is embodied both in the mandate of the Global Alliance and in various aspects of the COP5 Decision SC-5/6 on DDT. While much attention has been paid to developing safer chemical alternatives to DDT for insecticide use, the recent COP5 discussions also recognized that the potential contributions of non-chemical environmental-based interventions are significant and should not be overlooked.

Among the non-chemical alternatives mentioned at the COP5, microbial larvicides hold promise as a safe, effective, and environmentally sustainable component of a successful integrated vector management strategy. Historically, chemical larvicides such as Paris Green were used, but these pose significant risks to humans, other non-target species, and the environment. Modern preference for treatment of habitat is with the microbial agent of bacterial pathogens *Bacillus thuringinensis (Bti)* and *Bacillus sphaericus (Bs)*. Existing studies on microbial larviciding demonstrate not only its significant potential as a safe non-chemical alternative to DDT for disease vector control, but also highlight the immediate need for and value of greater research, particularly on innovative methods of larval source management as well as building a better understanding of the factors and contexts impacting the efficacy of different larviciding strategies.

The current baseline is characterized by an absence of specific knowledge and capacity for the formulation of evidence-based national policy elements in Tanzania to promote and support larval source management (LSM) in the early stage of the vector life cycle. As an understudied intervention, the full role of larviciding as a malaria control measure remains to be clarified, especially in rural areas. Both the integrated vector management (IVM) approach and literature on larviciding make clear that larviciding should never be a stand-alone approach, but rather explored as a promising complement to existing alternative malaria control methods. As the evidence for larviciding as an effective non-chemical malaria control alternative builds, there is a heightened need to contextualize and define its place in the complicated array of malaria control methods. In order for the full potential of larviciding to be realized, key stakeholders and decision-makers need more and clearer information on various parameters of its use, including its impact, cost-effectiveness, necessary coverage levels, potential synergistic effects, and sustainability.

An increase in investments and malaria control initiatives (especially LLINs and IRS) over the past two decades have translated to a significant reduction in the burden of malaria both globally and in Tanzania in particular. In mainland Tanzania, the WHO World Malaria Report reflects a rapid drop in estimated malaria cases from 11.54 million in 2006 (WMR 2008) to 1.55 million in 2013, the most recent year for which data is available (WMR 2014). While prevalence in Lower Moshi has also declined, malaria transmission in the Lower Moshi area has been classified as holo-endemic (Mahande, et al., 2012; Kulkarni et al.,2006) and one of the most common reasons for visiting a health facility in the area (Lowassa, et al., 2012). Among pregnant women presenting to select health facilities for antenatal care in the Kilimanjaro region of Lower Moshi between January and June 2015, malaria prevalence by facility ranged from 0.9% to 25%.

However, concerns about both insecticide and drug resistance threaten the ability to sustain these gains in the future. During the 2010-2013 period, 53 of 65 countries reporting to the WHO noted mosquitoes had developed resistance to at least one insecticide used for IRS and/or LLINs. Moshi is among a number of districts in Tanzania found to be experiencing resistance of malaria-transmitting mosquitoes to DDT-alternative insecticides in recent years (Kabula, et al., 2013; Matowo, et al., 2010). Emerging resistance to insecticides employed in these widely-used vector control methods could compromise their effectiveness and lead to a return to the use of DDT in place of the alternative insecticides currently employed in Tanzania. In fact, while DDT has not been used in Tanzania for some time, Tanzania's NIP expressed the intention of the Ministry of Health to use DDT for IRS, and Tanzania is one of the signatories of the recent Abuja Convention (2013) where African countries agreed to increase the use of DDT in malaria control. Thus, there is a real risk that Tanzania could resume use of DDT for vector control in the future, in which case it would not be without company – 8 African countries used a total of 337.9 tonnes of DDT for disease vector control in 2014. The best way to prevent the reintroduction of DDT for disease vector control in Tanzania is to develop and implement alternative methods which are safer, effective, contextually appropriate and sustainable. This strategy is embodied both in the mandate of the Global Alliance and in various aspects of the COP5 Decision SC-5/6 on DDT, which recognized the potential contributions of non-chemical environmental-based interventions.

The effectiveness of the microbial larvicide Bacillus thuringinensis (Bti) in drastically reducing the populations of mosquito larvae and adult mosquitoes in the surrounding area has been repeatedly demonstrated (Fillinger, et al., 2009; Magesa, et al., 2009; Majambere, et al., 2007; Geissbuhler, et al., 2009; Fillinger & Lindsay, 2006). Larviciding using Bti has been used in Tanzania, including in Dar es Salaam, Bagamoyo and Mvomero, and biological control using biolarvicides is included in the current Tanzania Medium Term Malaria Strategic Plan.

This project would make a novel contribution to the growing evidence base on microbial larviciding as a promising malaria vector control strategy by developing, implementing, and evaluating a novel community-based application approach that would enlist local farmers to apply an optimal larvicide-fertilizer mix to rice fields in a rural area. Should the project prove the method both effective and feasible, there would be opportunities to scale up this approach in rice-growing areas both in Tanzania and in other countries where malaria is endemic. In Tanzania, other main rice-growing areas experiencing significant malaria transmission include Shinyaga, Morogoro, Mwanza, Tabora, and Mbeya. In addition to its emphasis on evaluating the potential of a novel rural community-supported application method, this project would respond to a need to further explore, contextualize and define the place of larviciding in the complicated array of malaria control methods, by providing key stakeholders and decision-makers more and clearer information on various parameters of its use, including its impact, cost-effectiveness, necessary coverage levels, potential synergistic effects, sustainability, and scale-up.

A review undertaken by the study team in April 2015 evaluated both the literature as well as currently-funded projects in key databases (e.g., Gates Foundation, GFATM, GEF, WHO, DFID, NIH, USAID) and found no directly comparable studies of microbial larvicides being used to target larval source reduction in rice fields for malaria control through mixing larvicide with fertilizer for application, underscoring the novel nature of this proposal. However, a number of other projects have successfully applied a community-supported application strategy as proposed in this project (including the Urban Malaria Control Programme in Dar es Salaam, Tanzania; the Malaria Free Initiative in Khartoum, Sudan, the Urban Malaria Scheme, India; the Urban Malaria Control Program (UMCP) Malindi, Kenya). These programs are summarized in the WHO Operational Manual on larval source management (WHO, 2013).

A number of studies have evaluated the effects of Bti on the environment and humans and found it to be safe; to date, no negative effects on non-targeted organisms, including humans, have been linked to the use of Bti (Magesa, et al., 2009; Majambere et al., 2007; Eder & Schonbrunner, 2010). Bti has been used in many countries, including in Tanzania as listed above. The formulation of Bti which project partners used in the NIH study in Mvomero, and anticipate using in this study (*Bacillus thuringiensis var.*

israelensis (Bti) strain AM65-52) is approved and recommended by the WHO Pesticide Evaluation Scheme (WHOPES) for control of mosquito larvae (http://www.who.int/whopes/Mosquito_Larvicides_Sept_2012.pdf).

Project structure:

The project objective is integration of community-based microbial larviciding into the national IVM strategy. The project responds to the need for the creation of new knowledge and capacity building for improved policy formulation with regards to the deployment of non-chemical alternatives to DDT for disease vector control.

The principal operational component (project outcome) is creation of new knowledge about the cost-effectiveness and practicality of farmer application of microbial larviciding as an alternative to DDT and other chemical approaches to malaria control s. The project will seek to deepen the evidence base and mechanisms for attacking vector-borne diseases earlier in the vector life cycle through a novel application method of microbial larvicidal agents, as a safe and sustainable malaria control alternative to POPs like DDT. This novel method would enlist farmers to assist in malaria control efforts by applying an optimal larvicide-fertilizer mix to rice fields.

The project outcome will be pursued through four outputs and their related activities as follows, drawing on an active and inter-disciplinary network of researchers, practitioners, and policymakers to build research, monitoring, and analytical capacity to make more informed decisions about non-chemical alternative approaches to malaria prevention and treatment:

Output 1.1: Proof of concept and experimental plot studies designed and implemented in the Lower Moshi area of north-eastern Tanzania.

The main activity (Activity 1.1.1) related to this output is to apply varying applications of larvicide-fertilizer mix to determine the effects on mosquito larvae survival and agricultural productivity. First, proof of concept studies will be designed and implemented in a laboratory setting to determine the effects on mosquito larvae survival of varying concentrations of microbial larvicide mixed with fertilizer. Based on the results of the laboratory experiments, further studies will be conducted in semi field conditions in experimental plots to examine the effects of different concentrations and application strategies of a larvicide-fertilizer mix on mosquito larvae and agricultural productivity.

Output 1.2: Field experiments designed and implemented. Under this output, the project will undertake 2 activities:

- To train and supervise farmers on application of larvicide-fertilizer mix in their rice paddies (Activity 1.2.1)
- Evaluate feasibility and effectiveness of farmer application of larvicide-fertilizer mix (Activity 1.2.2).

The process will follow scientific principles related to the statistical significance of the approaches being trialed. This will include the definition of controls, the use of replicates, the selection of a large enough sample of plots and numbers of farmers to ensure results have a sound scientific basis. The overall design process will be presented at the inception meeting to ensure complete transparency.

Based on results of the proof of concept and experimental plot studies as well as preliminary qualitative research on community acceptance, experiments engaging rice farmers in the application of a larvicide-fertilizer mix in their fields will be designed and implemented in the Lower Moshi area of north eastern Tanzania. Local rice farmers in selected villages will be invited to participate in the application of a larvicide-fertilizer mix in their fields according to an appropriate schedule informed by proof of concept and qualitative community assessments. These activities will also include collecting baseline and follow-

up entomological data as well as qualitative data on knowledge, attitudes and practices, allowing for a more holistic consideration of effectiveness, feasibility, and acceptability of engaging farmers in larvicide application.

Output 1.3: Socioeconomic studies on local perceptions and attitudes towards larviciding and farmer application conducted.

To accomplish this output, the project will implement surveys, focus group discussions, key informant interviews, and community meetings (Activity 1.3.1). The project will assess community perceptions and attitudes on larviciding in general as well as the project larviciding activities through a variety of mechanisms. The project will conduct household surveys on knowledge, attitudes, and practices regarding malaria (including perceptions and acceptability of larval source management). In addition, the project will organize focus groups on larviciding activities, with an added emphasis on assessing perceptions and attitudes towards farmers' involvement in the application of larvicide. The findings will inform the study design as well as analysis on effectiveness and acceptability of farmer-assisted larvicide application.

Output 1.4: Disseminating of lessons learned and integrated into policy guidance. This output will be achieved through three activities:

- Incorporate analytical conclusions from the field experiments into an existing decision support tool (Activity 1.4.1): Under Activity 1.4.1, analytical conclusions from the experiments will be drawn upon to improve upon an existing decision support tool that includes both vector control and disease management alternative malaria control strategies. The project aims to incorporate its findings on larviciding into a product of a previous Medium-Sized Project (MSP) project (the Malaria Decision Analysis Support Tool, or MDAST) which developed a comprehensive decision-analysis framework for assessing the full range of health, social, and environmental risks and benefits associated with alternative malaria control strategies. The findings will make a valuable contribution to refining the related parameters as they operate in the MDAST model. As a result, the tool will be a more accurate and comprehensive aid to malaria control decision-makers by incorporating new knowledge on safe and sustainable alternatives to persistent organic pollutants like DDT.
- Disseminate the refined tool and provide training on its use through a workshop and conferences (Activity 1.4.2): Through Activity 1.4.2, a Policy Dialogue Workshop will be held with participants from key government ministries, non-governmental organizations, and research organizations to present an updated, user-friendly MDAST and to train decision-makers in its use. The exchanges and feedback from the workshop will be used to contextualize larviciding within the broader array of available malaria control alternatives incorporated into the MDAST model.
- Generate publications, outreach materials, and guidelines for replication and adaptation of larviciding intervention strategies (Activity 1.4.3): Under Activity 1.4.3, the project will disseminate project results and lessons learned, and develop guidelines for replication in other settings. Guidelines for replication and adaptation of larviciding intervention strategies to other malaria-prone countries as well as lessons learned will be disseminated through workshops, community meetings, and publications. This activity will be closely coordinated with the World Health Organization AFRO Region, which has been the executing agency for the previously mentioned MDAST project.

Output 1.4 also incorporates the necessary M&E reporting for the project.

Implementation arrangements:

The project will be implemented through a partnership of collaborating institutions as listed below, many of which have worked together on previous malaria projects in the region.

- Kilimanjaro Christian Medical College (KCMC) (Moshi, Tanzania), is actively engaged in malaria research in Tanzania and will be the Executing Agency for this project. KCMC will be responsible for overall management and coordination of subcontract partners and their performance, as overseen and directed by the Project Lead and Project Manager. The proposed Project Manager is currently attached to the KCMC College Pan African Malaria Vector Research Consortium (PAMVERC) program. The PM will be issued with a College contract to work full time on the project.
- Duke University (North Carolina, USA) has multiple malaria research projects ongoing in East Africa and will collaborate closely on all aspects of project management and execution.
- The National Institute for Medical Research – Tanzania (NIMR) (Dar es Salaam, Tanzania) is a parastatal organization and the largest public health research institution in Tanzania. NIMR will draw on its experience and results from an ongoing larvicide project to give advice on project design and implementation.
- The International Centre of Insect Physiology and Ecology (ICIPE) (Nairobi, Kenya) is a non-governmental organization (NGO) which focuses on entomological issues. The chief role of ICIPE in the project would be to advise on the design and implementation of the project as well as contribute to the incorporation of analytical inclusions into the existing decision support tool.
- The University of Michigan (Michigan, USA) will be chiefly responsible for data management and geographic information system (GIS) analysis, and will contribute to the field work design.
- The WHO served as the Executing Agency of the GEF-funded MDAST project under which the decision support tool was developed. The WHO will have an advisory role in the proposed project with regards to aspects of further tool refinement and awareness raising with relevant government institutions.
- The Kilimanjaro Agricultural Training Centre (KATC) (Moshi, Tanzania) is a locally-based institute which has cultivated long-standing relationships and trust with rice farmers in the area and will continue to support training, implementation, and reporting on the community-based larviciding activities after the conclusion of the project. KCMC will leverage its strong existing relationship with KATC, which will be closely involved in the training of local rice farmers as community-based larvicide applicators.

It should be noted that Duke University, the University of Michigan, ICIPE, and NIMR would all be subcontractors to KCMC for the project. KCMC has submitted a Due Diligence Checklist in support of its capacity to serve as Executing Agency on this project. Additional information regarding the research and management capabilities of KCMC, particularly with regards to managing projects with international funders and subcontractors, is provided below:

The Kilimanjaro Christian Medical University College is located on the Kilimanjaro Christian Medical Centre campus. The College was founded in 1997 and today there are more than 1500 students in the College pursuing 16 health-related degrees. The Kilimanjaro Christian Medical Centre is located on a 480-acre campus in Moshi Town and houses a 450 bed hospital, outpatient departments that attend to more than 500 patients per day, a central library, administrative offices, dormitories, and housing for international visitors. State-of-the-art computer facilities include computing labs with internet connections made through a satellite connection, printers and high speed scanners located on-site, and a back-up generator for power outages.

The KCMC-Duke collaboration began in 1995, and continues today as a well-established partnership for research, education, and service-learning. Full-time Duke faculty and staff are on the ground at KCMC. Beginning in 2002 with the first research grant funded by the US National Institutes of Health (NIH), Duke has developed substantial research and clinical collaboration, and now regularly has millions of

USD in research support per year. In 2010, the KCMC-Duke collaboration was granted funding from the NIH Fogarty Center to establish a Medical Education and Partnership Initiative (MEPI) site at KCMC. KCMC was the prime grant recipient, managing over US$5 millio total funding over 5 years (including a US$2.36 million subcontract to Duke University). Based on its strong performance, this project will continue activities under the MEPI-II project, which was recently awarded $UD640,000 per year for 5 years (US$3.2 million total), including subcontracts to Duke University, Cornell University (New York, USA), and Bugando Medical Centre (Mwanza, Tanzania). Throughout the long-standing Duke-KCMC collaboration, Duke has invested significant resources for capacity-building of KCMC financial management and grants management staff and systems, including working together to develop the Office of Research Management and Innovation (ORMI) at KCMC. KCMC also handles a significant amount of grant funding beyond the Duke-KCMC collaboration, including other malaria vector research collaborators such as the National Institute for Medical Research – Tanzania (NIMR), London School of Hygiene and Tropical Medicine, USAID, and the World Health Organization Pesticide Evaluation Scheme (WHOPES). KCMC is also a regional leader in research management and administration best practices, as epitomized by its role as founder and Secretariat of the Association of Research Administrators in Africa (ARAA) (http://araafrica.org/) which provides a forum for exchanging best practices and building professional capacity in research management and administration in Africa, particularly with regards to global health research and development.

The project will also establish institutional arrangements with key government and regional entities to obtain essential feedback and ensure consistency of project activities with these organizations priorities and strategies:

- The WHO-AFRO country office malaria program officer (Dr. Njau) will be involved in the project (including through participation in the inception workshop and annual steering committee meetings) and will collaborate on Pan-African Malaria Vector Research Consortium (PAMVERC) activities.
- At the national level, the project will coordinate with:

a. The Ministry of Health (MOH): The project will engage closely with the MOH of Tanzania, and the NMCP in particular, throughout project implementation but especially with regards to Output 1.4 (Disseminating of lessons learned and integrated into policy guidance) through the planned activities to disseminate and provide training on the refined decision support tool (Activity 1.4.2), and to generate guidelines for replication and adaptation of larviciding intervention strategies (part of Activity 1.4.3). At the district level, the Malaria Focal Person appointed by MOH will be involved in the field work activities in Lower Moshi.

b. The Ministry of Environment (MOE): Will also be engaged in project activities, including the involvement of the Regional Education Officer in sensitization meetings.

c. The Ministry of Agriculture (MOA): Will be involved through the participation of KATC.

Representatives from MOH/NMCP, MOE, and MOA will be included in annual PSC meetings along with representatives from farmer and community / civil society groups.

The role of the MOH/National Malaria Control Program (NMCP), MOE, and MOA in the project will be formalized during the inception workshop, to which government representatives from each entity will be invited. Representatives from each entity will also be invited to participate in annual Project Steering Committee meetings and engaged throughout project implementation. Formal engagement agreements for each entity will be signed by participating representatives, who would also contribute to the development of these statements during the inception workshop. The project will engage closely with the MOH of

Tanzania, and the NMCP in particular, throughout project implementation but especially with regards to Output 1.4 (lessons learned integrated into policy guidance) through the planned activities to disseminate and provide training on the refined decision support tool (Activity 1.4.2), and to generate guidelines for replication and adaptation of larviciding intervention strategies (part of Activity 1.4.3). At the district level, the Malaria Focal Person appointed by MOH will be involved in the field work activities in Lower Moshi. The Ministry of Environment will also be engaged in project activities, including the involvement of the Regional Education Officer in sensitization meetings. The Ministry of Agriculture will be involved through the participation of KATC. Through Activity 1.4.2, a Policy Dialogue Workshop will be held with participants from key government ministries, non-governmental organizations, and research organizations to present an updated, user-friendly MDAST and to train decision-makers in its use. WHO-AFRO will be involved in awareness raising with relevant government institutions, under the direction of the country office malaria program officer for Tanzania.

Throughout the project, partners will monitor and evaluate progress to ensure project success. The project partners will also participate where appropriate in facilitating and responding to the mid-term and terminal external project reviews.

A. 5. Incremental /Additional cost reasoning: describe the incremental (GEF Trust Fund/NPIF) or additional (LDCF/SCCF) activities requested for GEF/LDCF/SCCF/NPIF financing and the associated global environmental benefits (GEF Trust Fund) or associated adaptation benefits (LDCF/SCCF) to be delivered by the project:

Donor funding covered the majority (85%) of activities in the Tanzania NMCP strategic plan for 2008-2013 (Mboera et al., 2013), and there is no reason to expect a dramatic shift in this trend in the near future. Almost all (90%) of financing for malaria control in mainland Tanzania comes from The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and PMI. For the current allocation period 2014 – 2016, the Global Fund New Funding Model has allocated 185 million USD strictly for malaria control in mainland Tanzania (an additional 17 million USD was allocated within the total grant for related health system strengthening activities) (USAID, 2015); this averages to about 61.7 million USD per year. DFID has committed 36 million USD to combat malaria in Tanzania for the same period of 2014-2016 (USAID, 2015), or an average of 12 million USD per year. The PMI allocation for mainland Tanzania for FY2015 is 45 million USD (USAID, 2015). The other major donor contribution for malaria control in Tanzania comes from the Swiss Agency for Development & Cooperation for 6 million USD from 2013 – 2017 (USAID, 2015), or about 1.2 million per year. So, current funding for malaria control in mainland Tanzania from the major sources of external funding can be estimated at around 120 million USD per year. Historically, from 2000 – 2010, funding for malaria control in mainland Tanzania has been allocated largely for ITNs (48%) and diagnosis and treatment (30%), with lesser-funded strategies being IRS (8%), behavioral change (6%), M&E (5%), Other (2%), and IPTp (1%) (Mandike). Much of the funding is directed towards large-scale programming of well-established strategies, such as universal ITN coverage campaigns. While these campaigns are undoubtedly important, especially in the face of mounting insecticide resistance there is also a need for smaller-scale funding to support the development and evaluation of innovative approaches to malaria control, particularly in the under-funded area of integrated vector management. This project proposes to deepen the evidence base and mechanisms for attacking vector-borne diseases earlier in the vector life cycle through a novel application method of microbial larvicidal agents, as a safe and sustainable non-chemical malaria control alternative to persistent organic pollutants like DDT.

The project's objectives will be achieved through proof of concept studies, field experiments, and household surveys and focus group discussions, none of which would be possible without GEF funding for this project. This project adds an environmental component to a set of ongoing agricultural development activities in the lower Moshi area. Additional incremental activities would ensure that the

contributions of this project to the evidence base are incorporated into the policy-making process through multiple stakeholder-driven mechanisms which would require GEF funding. The governments of Tanzania and other malaria-endemic countries more broadly as well as civil society organizations have demonstrated strong commitments to curbing the malaria burden, but are faced with limited resources that constrain their ability to assess, build capacity, and implement non-chemical alternatives to DDT for malaria control. The GEF funding for this project would make it possible to build the evidence base for a novel method of larvicide application as an environmentally-friendly and sustainable non-chemical alternative to malaria control and to build related policy-making capacity. The total cost of the project is the amount necessary to achieve the project's outcomes, outputs, and health and environmental benefits beyond the current baseline scenario. The incremental cost for the project of 975,000 USD (agency fee not included) is requested of GEF. A total of 3,926,083 USD of co-financing is committed by project partners from a variety of sources, as detailed in Part I.C. of this document and as supported by co-finance letters from the committing institutions contained in Appendix 14.

Global Environmental Benefits:

The project has the potential to contribute to global environmental benefits on a number of levels. WHO-AFRO has reported that there were 8 African countries using a total of 337.9 tons of DDT in 2014 for disease vector control. While DDT is not currently being used in Tanzania, Tanzania's National Implementation Plan (NIP) for the Stockholm Convention expressed the intention of the Ministry of Health to use DDT for indoor residual spraying (IRS), and Tanzania is one of the signatories of the Abuja Convention (2013) where African countries agreed to increase the use of DDT in malaria control. The amount of DDT which Tanzania would be likely to import if it were to revert to DDT use (i.e., the amount of DDT which this project would contribute to averting) can be estimated at 22.6 tons per year (this is the average number of tons of DDT used in 2014 in each of two neighboring countries, Zambia and Mozambique). IVM policy, including incorporating the use of treated nets and larvicides, can reduce the pressures to include DDT in national malaria vector control policy by providing effective, sustainable alternatives. The discussion and decisions of the Fifth Meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants (COP5) have underscored the immediate need to increase support for researching, deploying, and raising awareness among key decision-makers about the importance of non-DDT alternatives in the battle against malaria.

The proposed project addresses key aspects of COP5 Decision SC-5/6 on DDT, especially the need for safe, effective, cost efficient, and environmentally sustainable non-chemical alternatives to DDT for the control of vector-borne diseases including malaria, and the imperative to provide support to developing countries for the implementation of such activities. The call for additional research on non-chemical alternatives was reiterated in the Report on COP6 (UNEP/POPS/COP.6/33) as well as during the proceedings of COP7, as summarized in the COP7 document, "Evaluation of the continued need for DDT for disease vector control and promotion of alternatives to DDT" (UNEP/POPS/COP.7/5). This document outlines a number of key elements related to implementing a road map for the development of alternatives to DDT with which the project is closely aligned, including the directives to "strengthen country and local capacities to…assess and deploy alternatives" (road map element 2.2) and "share experiences and upscaling the application of non-chemical alternatives" (road map element 2.4). The proposed project also directly responds to the mandate of The Global Alliance for the Development and Deployment of Products, Methods, and Strategies as Alternatives to DDT for Disease Vector Control to improve knowledge and evidence-based policy making on IVM including through the development of non-chemical alternatives to DDT for disease vector control. National programming and local populations will benefit by the more judicious use of its limited resources for malaria control afforded by the strengthened evidence base. The project will improve knowledge and the global evidence base regarding feasibility, community acceptance, and effectiveness of microbial larviciding as a support to national policy formulation. The multiple potential benefits of larviciding reiterate the need for a multi-pronged IVM

approach to malaria control; a package of varied malaria interventions addressing different stages and aspects of the disease and its management will have a greater impact and may also serve as a powerful strategy for resistance management. In reducing the barriers to acceptance and use of a promising non-chemical alternative to DDT while strengthening in-country decision-making on aspects of integrated vector management, the project will yield global benefits to the environment and human health by addressing the malaria burden and contributing to the phasing out of DDT use and its releases into the environment. The project will also develop guidelines for replication and adaptation of findings to other settings to expand the reach and applicability of the human health and environmental benefits of the project. At the national level, the project would allow for greater assessment and consideration of a promising non-chemical alternative to DDT for malaria control, addressing a knowledge gap that the National Malaria Control Program has not had the resources to fully address on its own. The activities under project outcome 1.4, which include the collaborative refinement and training on an existing decision-support framework as well as guidelines for replication, would directly contribute to enhanced national capacity among key in-country malaria control policymakers to make improved evidence-based decisions and strategies at regional, national, and sub-national levels.

A.6 Risks, including climate change, potential social and environmental risks that might prevent the project objectives from being achieved, and measures that address these risks:

The project approach includes consideration of how to mitigate identified risks. These are summarized in the risk log below, also included as Appendix 3. First, there is a logistical and technical risk at the local and national levels that microbial larviciding in general and a farmer-assisted larviciding strategy in particular may not be a sufficiently efficacious, effective, feasible, and/or sustainable alternative to the use of DDT for malaria control; this risk is mitigated by a growing body of research demonstrating the value and significant potential of microbial larviciding as a non-chemical approach to malaria vector control in combination with other non-DDT malaria control strategies. The willingness of rice farmers to apply the larvicide-fertilizer mix on their fields is essential; the human risk at the local level that they may not readily support the initiative, is mitigated by the strong relationship that Kilimanjaro Christian Medical College (KCMC) has with the Kilimanjaro Agricultural Training Centre (KATC), a locally-based institute which trains and is trusted by local rice farmers. Another main assumption for successful implementation of the project is that key stakeholders and communities are willing to consider incorporating microbial larviciding into a broader IVM approach to disease vector control; the risk that this may not be the case could be categorized as a political and organizational risk present at all levels (global, regional, national, and local). It is assumed that policy makers will be willing to take into account project-generated data and guidelines on larviciding in making informed policy decisions. The assumption regarding willingness to incorporate microbial larviciding into the IVM approach to malaria control is based on existing studies and reports. The risk that policy makers will be unengaged in or unwilling to take into account project results is minimized due to existing partnerships. The risk that policy makers would be unwilling to use the revised decision-making tool (MDAST) to inform policy decisions is mitigated by the engagement of policy makers in Tanzania and East Africa more broadly in the development and dissemination of the existing decision-making tool.

RISK LOG						
Risk Description	**Level**	**Category**	**Impact Severity**	**Likeli-hood**	**Risk Management Strategy & Safeguards**	**By When/ Whom?**
Political barriers to disseminating & implementing replication and adaptation guidelines; key stakeholders and communities not willing to consider incorporating microbial larviciding into a broader IVM approach to disease vector control.	All levels (Global, regional, national, and local)	Political, Organizational	High	Low	A Policy Dialogue Workshop will facilitate discussion among key malaria control stakeholders, drawing upon and strengthening existing partnerships and networks. Project results will be incorporated into an existing decision support tool to support evidence-based policymaking.	Year 3 of project / all project partners and key malaria control stakeholders
Farmer-assisted larviciding in rice paddies not a viable and effective method	Local, national	Logistical, technical	High	Medium	Proof of concept studies and experimental plot studies will determine optimal concentration and application factors and establish viability and effectiveness in those settings before full-scale field implementation.	Year 1 of project / KCMC
Farmers will not support and engage in the proposed larvicide application method	Local	Human	High	Low	Community sensitization and household surveys on community acceptability of farmer-assisted larviciding will inform project partners of barriers and provide opportunities to address them.	Year 1 of project / KCMC, NIMR, Duke University

A.7. Coordination with other relevant GEF financed initiatives

The proposed project aims to incorporate its findings on larviciding into a tool developed through a recently completed Global Environment Facility (GEF) funded medium-sized project (MSP) (the Malaria Decision Analysis Support Tool, or MDAST) which developed a comprehensive decision-analysis framework for assessing health, social, and environmental risks and benefits associated with alternative vector control and disease management malaria control strategies. This project will benefit from and respond to the recommendations and needs of a rich and diverse network of key stakeholders that were engaged in the development, dissemination, and implementation of MDAST. MDAST was developed through a partnership of collaborators including the World Health Organization (WHO) (the executing agency), agencies in each of the three project countries (the Ministry of Health in Uganda, the Ministry of Health in Kenya, and the National Institute for Medical Research (NIMR) in Tanzania), Duke University, and the University of Pretoria. Through Activity 1.4.2, a Policy Dialogue Workshop will be held with participants from key government ministries, non-governmental organizations, and research organizations to present an updated, user-friendly MDAST and to train decision-makers in its use. The exchanges and

feedback from the workshop will be used to contextualize larviciding within the broader array of available malaria control alternatives incorporated into the MDAST model.

The proposed role of MDAST in this project responds to recommendations made in the Terminal Evaluation of the MDAST MSP project, including "that resources [be] made available (through follow up projects currently being developed) for further adequate training to properly build the capacity of stakeholders / policy makers on the use of MDAST", "that actions [be] taken at national level to promote the use of MDAST for any future decision making on malaria control" and "to promote adequate visibility of the [MDAST] project to ensure linkages between MDAST and on-going malaria control initiatives".

The project will link with regional efforts by WHO and UNEP to promote the adoption of IVM. By developing and assessing the effectiveness of a novel community-based application method of microbial larvicide in a rice irrigation setting, the proposed project will complement the GEF/UNEP regional project titled "Demonstrating Cost-effectiveness and Sustainability of Environmentally Sound and Locally Appropriate Alternatives to DDT for Malaria Vector Control in Africa" (known as "AFRO I") and the related proposed FSP, "Demonstration of Effectiveness of Diversified, Environmentally Sound and Sustainable Interventions, and Strengthening National Capacity for Innovative Implementation of IVM for Disease Prevention and Control in the WHO AFRO Region" (known as AFRO II). Within mainland Tanzania, the AFRO II project emphasizes that "vector control other than LLIN should be based on evidence on feasibility and effectiveness" and highlights a need to delay insecticide resistance.

The AFRO II plan for mainland Tanzania also prescribes systematic monitoring and evaluation of larviciding trials to further define the place of larviciding in the national malaria vector control strategy, but also notes the limitations of in-country capacity. A key aim of the AFRO II project activities in Tanzania is to further efforts to "diversify the vector control strategy based on evidence". The proposed project avoids duplication as its particular novel approach is not under consideration by AFRO II, yet is nonetheless complementary to its objectives, including building the evidence base for under-studied vector control approaches, and strengthening in-country capacity. This project would uniquely contribute to the evidence base for policy discourse on microbial larviciding as a viable, sustainable, and environmentally safe vector control method for a range of rural and agricultural scenarios in eastern Africa. Moreover, the overlap in partnerships between the proposed project and AFRO-II – both count University of Pretoria and Duke University among their planned partners, in addition to in-country stakeholders – would not only ensure duplication is avoided but also provide opportunities for collaboration and synergy between projects. For example, Duke University's proposed involvement in the AFRO-II project would include additional support for expanding training on MDAST.

The research would also offer opportunities for rich comparisons with a study in the Mvomero district of Tanzania funded by the United States-based National Institutes of Health in which Duke University, NIMR, and the University of Pretoria are involved. Within that study, local people hired to apply *Bacillus thuringiensis israelensis* (Bti) microbial larvicide in their communities have been trained by project staff to identify and treat larval habitats for malaria vector mosquitoes in 12 villages.

B. ADDITIONAL INFORMATION NOT ADDRESSED AT PIF STAGE:

B.1 Describe how the stakeholders will be engaged in project implementation.

In order for the full potential of larviciding to be realized (i.e., replicable, scalable, and sustained), key stakeholders including high-level policy makers need more and clearer information on various parameters

of its use, including its impact, cost-effectiveness, necessary coverage levels, potential synergistic effects, sustainability, etc. The experience and networks of the project partners will ensure national ownership and facilitate the project's aim to build decision-making capacity among policy-makers with regards to larvicide.

At an operational level, key stakeholders will serve on the PSC, which will meet annually to review and discuss project implementation status and plans. PSC members will include representatives from WHO-AFRO, MOH, MOE, and MOA, in addition to project partners KCMC, Duke University, NIMR, ICIPE, and University of Michigan. PSC members will also be in close communication throughout project planning and implementation, including via email and remote conferencing on a regular (monthly) and "as-needed" basis.

The project has incorporated a range of specific activities to engage key malaria control stakeholders and decision makers in full consideration of microbial larviciding as a non-chemical alternative malaria control strategy. Activity 1.4.3 of the project focuses on dissemination of project results and lessons learned, as well as guidelines for replication and adaptation of larviciding intervention strategies to other malaria-prone countries. Project partners will raise awareness of project activities and results among stakeholders through publications, at conferences, and via the guidelines. Under Activity 1.4.1, the existing decision support tool will be refined based on project results, and through Activity 1.4.2 a Policy Dialogue Workshop will be held with participants from key government ministries, non-governmental organizations, and research organizations to present the updated tool and train decision-makers in its application. In addition, throughout the project an existing website for the decision support tool (hosted at http://sites.duke.edu/mdast/) will be maintained and updated to serve as a resource to stakeholders interested in the tool and its use. These activities will be closely coordinated with the World Health Organization AFRO Region, which has been the executing agency for the previously mentioned MDAST project. The project will also engage closely with the MOH, including the NMCP, in particular on Activity 1.4.2 and Activity 1.4.3. At the district level, the Malaria Focal Person appointed by MOH will be involved in the field work activities in Lower Moshi. The MOE will also be engaged in project activities, including the involvement of the Regional Education Officer in sensitization meetings. The MOA will be involved through the participation of KATC. Through these processes, the project partners will continue to build strong relationships and networks among the key stakeholders, facilitating continued policymaking discussions on integration of larviciding into malaria control programming beyond the project period.

The project also considers farmers and local communities as key stakeholders both in the implementation of the project itself (through local involvement in larviciding application) as well as the end beneficiaries of the project outcomes which ultimately seek to improve the health of the community members and the environment around them through reductions in both the malaria burden, and DDT use. The project includes assessments of community acceptability of microbial larvicide interventions.

B.2 Describe the socioeconomic benefits to be delivered by the Project at the national and local levels, including consideration of gender dimensions, and how these will support the achievement of global environment benefits (GEF Trust Fund/NPIF) or adaptation benefits (LDCF/SCCF):

The cost of malaria across Africa has been estimated at around US$12 billion annually, factoring in health expenditures, lost productivity and school days due to illness, and impacts on tourism and investment (Gallup & Sachs, 2001). The "economic growth penalty" in African countries burdened by malaria may reach 1.3% per year (WMR, 2008). The negative effects of endemic malaria are felt not only in the health, investment, and tourism sectors but also extend to agriculture, where malaria can negatively impact crop and land use patterns as well as productivity (WMR, 2008).

Given the significant economic toll of the burden of malaria in Tanzania, the country and its population stand to gain substantial social and economic benefits from the implementation of effective and sustainable malaria control strategies. In a resource-poor environment, high expenditures due to malaria create a burden at both the government and household levels and prevent the use of these funds for other national development objectives as well as impact economic growth overall. Nationally, spending related to malaria has been estimated to make up 39% of total health expenditures, and over 1% of the country's GDP (Jowett & Miller, 2005). The same study reported that malaria demands nearly one-third of government health facility resources. Another study (Sicuri, et al., 2013) reported the average cost to treat a case of child malaria at $6.79, with the majority (55%) of these expenditures borne by the household. This study also noted the significant economic impact of foregone earnings due to childhood death from malaria.

At the national level, the project would allow for greater assessment and consideration of a promising non-chemical alternative to DDT for malaria control, addressing a knowledge gap that the National Malaria Control Program has not had the resources to fully address.

Initial approximations suggest that larviciding is not only cost-effective, but also cost-competitive with other alternative malaria control strategies. The potential benefits of larviciding reiterate the need for a multi-pronged IVM approach to malaria control; a package of malaria interventions addressing different stages and aspects of the disease and its management will have a greater impact. Larviciding has been shown to effectively complement other malaria control methods such as mass ITN distribution.

The significant potential of larviciding as a sustainable, non-chemical alternative to DDT for disease vector control highlights the immediate need for and value of greater research, particularly on innovative methods of larval source management. Community-supported programming has the potential to improve the sustainability and scope of larviciding as an alternative malaria control method. National programming and local populations will benefit by the more judicious use of its limited resources for malaria control afforded by the strengthened evidence base. At the local level, malaria can have a pronounced effect on household economic status due to the costs of seeking treatment as well as workdays lost. These factors can lead to national impacts such as lower growth rates in GDP.

The project will work in its initial stages to assess potential impacts and benefits on vulnerable groups, including children under five and women. Malaria morbidity and mortality rates are often more pronounced among pregnant women and children, who are also more vulnerable to the effects of the disease. The risk that malaria poses to these vulnerable populations could be reduced by the development of additional sustainable and effective alternatives to malaria control. The project will examine potential impact of community-supported microbial larvicide application and associated policymaking on women and children under five in particular. Studies have suggested that in some contexts women may be more exposed to insecticides including DDT when used in IRS due to increased time spent in and around the home (in theory, the same rationale would apply to exposure of children under five), which could mean that the focal area outcomes of a reduction in DDT production, use, and release on a global level could have a particular significance for reducing risks for these vulnerable groups.

Prevailing gender roles impact a range of factors related to malaria vector exposure and transmission risk, including activity patterns (i.e., location and timing of work and leisure activities) and sleeping arrangements (WHO, 2007). For example, previous work by project partners in Mvomero, Tanzania suggests that during peak periods of agricultural activity in rice paddies, male farmers are more likely to sleep outside the home in informal structures nearer their rice fields, increasing their risk of exposure to malaria-transmitting mosquitoes which bite at night (the informal structures offer less vector protection, and there is likely less consistent use of bednets in these temporary sleeping spaces). Women may be more exposed to IRS insecticides due to gender norms tied to increased time spent in and around the home. Pregnant women are at higher biological risk for severe malaria due to reduced immunity, and adverse birth outcomes are higher among pregnant women with malaria (Reuben, 1993). Gender norms may also result in unequal access to treatment for malaria, either because of reduced decision-making ability (e.g., use of funds) in the household, or because of constraints on mobility and/or time associated with household chores and childcare responsibilities (WHO, 2007, Lampietti et al, 1999)). There is a need for more research and information across a range of settings on the role of gender in malaria prevention and treatment practices (WHO, 2007).

As noted above the project will: work in its initial stages to assess potential impacts and benefits on vulnerable groups, including women given that malaria morbidity and mortality rates are often more pronounced among pregnant women; and, examine potential impact of community-supported microbial larvicide application and associated policymaking on women and children under five in particular. In addition, Output 1.3 (Socioeconomic studies on local perceptions and attitudes) will include focus group discussions separated by gender as well as key informant interviews with both men and women in order to be able to assess any differential malaria prevention, treatment, and knowledge base differences by gender, as well as implications of these differences for the project activities and policymakers. The project will also draw on results from focus group discussions conducted in the earlier Mvomero study in Tanzania that many of the current project partners were involved in to inform the socioeconomic studies to be conducted under this project.

B.3. Explain how cost-effectiveness is reflected in the project design:

The project seeks to assess the viability of community-supported microbial larviciding for malaria control as an alternative to DDT use. Cost-effectiveness is an essential consideration in determining the full potential of microbial larviciding as a viable alternative to DDT. Reflecting this, the first of the main outcomes of the project is the "creation of new knowledge about the cost-effectiveness and practicality of farmer application of microbial larviciding as an alternative to DDT and other chemical approaches to malaria control". Initial approximations suggest that larviciding is both cost-effective and cost-competitive with other malaria control strategies, but there remains a need to provide decision-makers with more information, particularly in rural settings. The novel community-based application approach of this project has the potential to improve the sustainability and scope of larviciding as an alternative to DDT for malaria control.

C. DESCRIBE THE BUDGETED M &E PLAN:

Please also reference Appendix 6 for additional information, including the Indicative Monitoring and Evaluation Work Plan and Corresponding Budget.

UNEP will be responsible for managing the mid-term review/evaluation and the terminal evaluation. The Project Manager and partners will participate actively in the process.

The project will be reviewed or evaluated at mid-term. The purpose of the Mid-Term Review (MTR) or Mid-Term Evaluation (MTE) is to provide an independent assessment of project performance at mid-term, to analyze whether the project is on track, what problems and challenges the project is encountering, and which corrective actions are required so that the project can achieve its intended outcomes by project completion in the most efficient and sustainable way. In addition, it will verify information gathered through the GEF tracking tools.

The PSC will participate in the MTR or MTE and develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented. An MTR is managed by the UNEP Task Manager. An MTE is managed by the Evaluation Office (EO) of UNEP. The EO will determine whether an MTE is required or an MTR is sufficient.

An independent terminal evaluation (TE) will take place at the end of project implementation. The EO will be responsible for the TE and liaise with the UNEP Task Manager throughout the process. The TE will provide an independent assessment of project performance (in terms of relevance, effectiveness and efficiency), and determine the likelihood of impact and sustainability. It will have two primary purposes:

(i) to provide evidence of results to meet accountability requirements, and

(ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP and executing partners.

While a TE should review use of project funds against budget, it would be the role of a financial audit to assess probity (i.e. correctness, integrity etc.) of expenditure and transactions.

The TE report will be sent to project stakeholders for comments. Formal comments on the report will be shared by the EO in an open and transparent manner. The project performance will be assessed against standard evaluation criteria using a six point rating scale. The final determination of project ratings will be made by the EO when the report is finalised. The evaluation report will be publicly disclosed and will be followed by a recommendation compliance process.

The direct costs of reviews and evaluations will be charged against the project evaluation budget. The detailed M&E budget is included as Annex G.

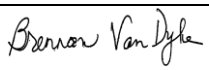
PART III: APPROVAL/ENDORSEMENT BY GEF OPERATIONAL FOCAL POINT(S) AND GEF AGENCY(IES)

A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT(S) ON BEHALF OF THE GOVERNMENT(S):): (Please attach the Operational Focal Point endorsement letter(s) with this form. For SGP, use this OFP endorsement letter).

NAME	POSITION	MINISTRY	DATE *(MM/dd/yyyy)*
Julius Ningu	Director of Environment	VICE PRESIDENT'S OFFICE, TANZANIA	09/20/2013

B. GEF AGENCY(IES) CERTIFICATION

This request has been prepared in accordance with GEF/LDCF/SCCF/NPIF policies and procedures and meets the GEF/LDCF/SCCF/NPIF criteria for CEO endorsement/approval of project.

Agency Coordinator, Agency Name	Signature	Date *(Month, day, year)*	Project Contact Person	Telephone	Email Address
Brennan Van Dyke		15/09/2015	Kevin Helps	254-20-76223140	Kevin.Helps@unep.org

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ANNEX A: UNEP LOGICAL FRAMEWORK (either copy and paste here the framework from the Agency document, or provide reference to the page in the project document where the framework could be found).

The UNEP Logical Framework below is also included as Appendix 5 in the separate Appendices document.

Project Objective	**Objective Level Indicators**	**Baseline**	**Targets and Monitoring Milestones**	**Means of Verification**	**Assumptions & Risks**	**UNEP MTS Reference**
Integration of community-based microbial larviciding into the national IVM strategy	Number of policy reports, statements, workshops, and meetings in which consideration is given to microbial larviciding as an alternative to DDT in malaria vector control	Insufficient evidence and knowledge base regarding viability of community-based microbial larviciding for malaria vector control Microbial larvicide a lesser-acknowledged/considered malaria vector control alternative by malaria control policymakers Microbial larvicide a lesser-used intervention for malaria control, especially with regards to community-based and rural applications	Year 1: Project Inception Workshop conducted Year 3: Strategy Report targeting the incorporation of larviciding into IVM strategy and Guidelines for replication and adaptation of larviciding intervention strategies developed and disseminated Year 3: Stakeholder Policy Dialogue Workshop conducted	Report on Project Inception Workshop Strategy Report & Guidelines included in final project report Report on Stakeholder Policy Dialogue Workshop	Risk: Political barriers to disseminating & implementing replication and adaptation guidelines Assumption: Key stakeholders willing to consider incorporating microbial larviciding into a broader IVM approach to disease vector control.	EA1: Enabling Environment & EA2: Chemicals
Project Outcome	**Outcome Indicators**	**Baseline**	**Targets and Monitoring Milestones**	**Means of Verification**	**Assumptions & Risks**	**MTS Expected Accomplish-ment**
1. Creation of new knowledge about the cost-effectiveness and	Number of farmers applying a larvicide-	No farmers applying a larvicide-fertilizer mix	Year 3: Number of farmers applying a larvicide-fertilizer mix: 1400	Terminal Project Report	Assumptions: the application of a microbial larvicide-fertilizer mix,	EA1: Enabling Environment &

practicality of farmer application of microbial larviciding as an alternative to DDT and other chemical approaches to malaria control	fertilizer mix				including through farmer-assisted application in rice paddies, is a viable and effective method for malaria vector control. Risk: The application of a microbial larvicide-fertilizer mix, including through farmer-assisted application in rice paddies, is *not* a viable and/or effective method for malaria vector control. Risk: Farmers will not support and engage in applying the larvicide-fertilizer mix	EA2: Chemicals For 2016 – 2017: EA (b), output 2 (*Portfolio of GEF-funded projects in support of Stockholm Convention*).

Project Outputs	**Output Indicators**	**Baseline**	**Targets and Monitoring Milestones**	**Means of Verification**	**Assumptions & Risks**	**PoW Output Ref. Number**
1.1. Proof of concept and experimental plot studies designed and implemented	Number of proof of concept studies completed Number of experimental plots evaluated Number of approaches confirmed as having a	No proof of concept studies or experimental plot studies examining effectiveness of different microbial larvicide-fertilizer mixtures	Year 1: Number of different mixtures to be evaluated through proof of concept studies: 4 replicates of fertilizer alone, 3 concentrations of Bti alone, and 3 concentrations of Bti + fertilizer Number of experimental plots evaluated: 4 replicates of fertilizer alone and fertilizer + best performing mixture.	Report on effects of different applications of larvicide-fertilizer mix in proof of concept (laboratory) and experimental plot settings	Risk: Certain applications of a larvicide-fertilizer mix may have potential negative impacts on agricultural productivity Assumption: The proof of concept holds true.	EA1: Enabling Environment & EA2: Chemicals

	positive impact and able to be replicated at field level.		Number of approach(es) confirmed as having a positive impact and applicable at field level: at least 1.			
1.2. Field experiments designed and implemented	Number of farmers trained and supervised on application of larvicide-fertilizer mix in their rice paddies Number of rice fields and entomological collection sites for which data is evaluated (to assess feasibility and effectiveness of farmer application of larvicide-fertilizer mix)	No field experiments examining farmer-assisted larviciding in rice paddies	Year 1: Number of households for which baseline entomological data collected: 48 sentinel houses Years 2-3: Total number of farmers trained: 2800 (including in control villages) Number of rice fields where experiments implemented: Total of 1400 plots Years 2-3: Number of sites for which follow-up entomological data collected and evaluated: 48 sentinel houses in both Years 2 & 3	Report on feasibility and effectiveness of farmer assisted larviciding	Risk: Farmers will not support and engage in the proposed larvicide application method	EA1: Enabling Environment & EA2: Chemicals
1.3. Socio-economic studies on local perceptions and attitudes towards larviciding and farmer application conducted	Number of surveys, focus group discussions, key informant interviews, and community meetings conducted. Data disaggregated to provide gender specific data.	Little knowledge on acceptability of larviciding and specifically farmer-assisted application of larvicide among local communities and farmers specifically	Years 1-2: Number of Household surveys on knowledge, attitudes, and practices regarding malaria (including perceptions and acceptability of larval source management) conducted: 600 in each of 2 Years Number of focus groups conducted: 4 Focus group discussions per intervention village, Total = 8 in each of 2 years Number of key informant	Report on assessment of local acceptability of larviciding application by farmers and education strategies based on the results of household surveys on knowledge, attitudes and practices	Assumption: Members of the local community are willing to participate in the socioeconomic studies	EA1: Enabling Environment & EA2: Chemicals

			interviews conducted: 9 in each of 2 years (3 Interviews per group (Leaders, Health workers, Agricultural field workers) Two community meetings involving demonstrations on larviciding activities in each of the 2 selected intervention villages conducted.	regarding malaria (including perceptions and acceptability of larval source management).		
1.4. Disseminating of lessons learned and integrated into policy guidance	Number of stakeholders trained on use of revised decision support tool and engaged in seminars on ways to incorporate larviciding into the overarching IVM strategy Number of publications reporting on project results and lessons learned Number of guidelines for replication and adaptation of larviciding intervention strategies	Need for systematic, evidence-based mechanism to allow policymakers to consider community-assisted larviciding in comparison and in combination with other malaria control alternatives	Year 1: Outreach and communications materials developed and disseminated to 5 target groups / communities. Year 1 & 3: Number of community meetings held: 8 (4 in Year 1 and 4 in Year 3) Year 3:Number of stakeholders trained in use of refined decision support tool and engaged in seminars on ways to incorporate larviciding into the overarching IVM strategy: 20 Year 3: Number of sets of guidelines for replication and adaptation of larviciding intervention strategies to other malaria-prone countries developed: 1 Year 3 and beyond: Number of manuscripts and conference abstracts published: 5	Materials published; Improved stakeholder driven decision support tool Guidelines for replication and adaptation of larviciding intervention strategies in other settings. Publications and other dissemination mechanisms reflecting results and guidelines.	Assumption: The results from outputs 1.1., 1.2. and 1.3 support the recommendation that microbial larviciding be integrated into vector management (IVM) strategy	EA1: Enabling Environment & EA2: Chemicals

ANNEX B: RESPONSES TO PROJECT REVIEWS (from GEF Secretariat and GEF Agencies, and Responses to Comments from Council at work program inclusion and the Convention Secretariat and STAP at PIF).

Please see separate attachments.

ANNEX C: STATUS OF IMPLEMENTATION OF PROJECT PREPARATION ACTIVITIES AND THE USE OF FUNDS[5]

A. PROVIDE DETAILED FUNDING AMOUNT OF THE PPG ACTIVITIES FINANCING STATUS IN THE TABLE BELOW:

PPG Grant Approved at PIF: **NA**			
Project Preparation Activities Implemented	***GEF/LDCF/SCCF/NPIF Amount ($)***		
	Budgeted Amount	***Amount Spent Todate***	***Amount Committed***
Total	0	0	0

[5] If at CEO Endorsement, the PPG activities have not been completed and there is a balance of unspent fund, Agencies can continue undertake the activities up to one year of project start. No later than one year from start of project implementation, Agencies should report this table to the GEF Secretariat on the completion of PPG activities and the amount spent for the activities.

ANNEX D: CALENDAR OF EXPECTED REFLOWS (if non-grant instrument is used**)**

Provide a calendar of expected reflows to the GEF/LDCF/SCCF/NPIF Trust Fund or to your Agency (and/or revolving fund that will be set up)

NA