MINUTES OF MEETINGS BETWEEN THE JAPANESE DETAILED PLANNING SURVEY TEAM AND THE AUTHORITIES CONCERNED OF THE GOVERNMENT OF THE REPUBLIC OF KENYA ON JAPANESE TECHNICAL COOPERATION FOR DEVELOPMENT OF RAPID DIAGNOSTIC TEST KITS IN KEMRI AND THE ESTABLISHMENT OF AN ALERT SYSTEM FOR OUTBREAKS OF PRIORITY ARBOVIRUSES IN KENYA

Japan International Cooperation Agency (hereinafter referred to as "JICA") organized the Detailed Planning Survey Team (hereinafter referred to as "the Team"), headed by Dr. Mitsuhiro Ushio, Executive Technical Advisor to the Director General, Human Development Department, JICA from August 23 to September 2, 2011 for the purpose of discussing the framework of the technical cooperation project entitled "Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arboviruses in Kenya" (hereinafter referred to as "the Project").

During their stay in Kenya, the Team had a series of discussions and exchanged views on the Project with the authorities concerned of the Republic of Kenya.

As a result of the discussions, the Team and the Kenyan authorities concerned agreed on the matters referred to in the document attached hereto.

Nairobi, September 2, 2011

Dr. Mitsuhiro Ushio
Team Leader
Japan International Cooperation Agency
Japan

Mr. Mark Bor
Permanent Secretary
Ministry of Public Health and Sanitation
Republic of Kenya

Dr. Solomon Mpoke
Director
Kenya Medical Research Institute
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THE ATTACHED DOCUMENT

I OBJECTIVES OF THE DETAILED PLANNING SURVEY

The objectives of the survey were to confirm background and contents of the request from the Government of the Republic of Kenya and to make a cooperation plan (project design) through discussions with the Kenyan authorities concerned. The Team also collected and analyzed necessary information for ex-ante evaluation.

The contents of the survey were as follows:

1. To confirm the contents and changes of the request from the Government of the Republic of Kenya and the research plan of the Nagasaki University, Institute of Tropical Medicine (hereinafter referred to as "NUITM") and to harmonize the two,
2. To have discussions with the Kenyan authorities concerned such as Ministry of Public Health and Sanitation (hereinafter referred to as "MOPHS") and Kenya Medical Research Institute (hereinafter referred to as "KEMRI") on the project design (including Project Design Matrix (hereinafter referred to as "PDM"), tentative Plan of Operation (hereinafter referred to as "PO"), and implementing scheme and structure), and to reach an agreement,
3. To confirm the current situation on ethical aspect, structure of approval, and implementation for research activities,
4. To confirm actions and schedule up to the Project's commencement ;and
5. To exchange the Minutes of Meetings (hereinafter referred to as "M/M") containing the project design and draft Record of Discussions (hereinafter referred to as "R/D"), which is to be signed before commencement of the Project as a token of confirmation of result of the discussions.

II BASIC FRAMEWORK OF THE PROJECT

1. Project Implementation Scheme

Both sides confirmed that the Project should be implemented under the 'Science and Technology Research Partnership for Sustainable Development*'

as shown in Annex I, promoted by JICA in collaboration with Japan Science and Technology Agency (hereinafter referred to as "JST").

JICA will take necessary measures for the technical cooperation such as dispatch of experts, provision of equipment and training of personnel, and other supports related to the Project. JST will support NUITM for the project activities implemented in Japan.

KEMRI will take necessary measures for technical cooperation, such as preparation of research facilities, equipment and materials, personnel, utilities, and other support related to the Project.

*"Science and Technology Research Partnership for Sustainable Development" aims to develop new technology and its applications, and also aims at capacity development of researchers and research institutions in both countries.

2. Project Title

Both sides recognized the significance of strengthened response to priority arboviruses, and agreed that it was appropriate to modify the project title from the one indicated in the application entitled "Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arboviruses in Kenya" to "the Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya" so that the agreed contents of the Project are more accurately reflected.

Both sides will propose the title modification to the authorities concerned of each government and, if approved, the title will be changed officially through diplomatic procedure.

3. Term of Cooperation

The duration of the Project will be five (5) years from the date, which will be indicated in R/D.

4. Administration of the Project

4-1. Administration

Both sides agreed that the administration of the Project will be organized as shown in Annex II and as follows.

There will be:

(1) Project Director (who will bear overall responsibility for the administration and implementation of the Project): Director, KEMRI,

(2) Project Manager (who will be responsible for the managerial and technical matters of the Project): Director, KEMRI-Centre for Infectious and Parasitic Diseases Control Research (CIPDCR) (Alupe),

(3)Project Co-managers (who will be responsible for the managerial and technical matters of the Project in collaboration with the Project Manager):
- Director of Department of Diseases Prevention and Control, MOPHS,
- Production Manager of Production Department, KEMRI; and
- Head of Arbovirology and Viral Hemorrhagic Fevers Laboratory, KEMRI.

(4) KEMRI counterpart researchers, as shown in Annex III,

(5) MOPHS counterpart personnel, as shown in Annex III,

(6) Chief Advisor (who will provide necessary recommendations and advice to the Project Director and the Project Manager and the Project Co-manager on any matters pertaining to the implementation of the Project),

(7) JICA Project Coordinator (who will coordinate the Project, supporting the Chief Advisor); and

(8) Other JICA Experts (who will give necessary technical guidance and advice to KEMRI counterpart researchers and MOPHS personnel on technical matters pertaining to the implementation of the Project).

4-2. Joint Coordinating Committee

For the effective and successful implementation of technical cooperation for the Project, a Joint Coordinating Committee will be established whose functions and composition are described as follows:

(1) Functions

1) To formulate and authorize the annual activity plan of the Project,

2) To endorse major achievements and products of the Project,

3) To monitor and review overall progress and supervise the Project; and

4) To review and discuss on major issues arising from or concerning the Project.

(2) Composition

1) Chairperson: Project Director

2) Members:

-Kenyan side

Project Manager, Project Co-managers

KEMRI counterpart researchers

MOPHS counterpart personnel

-Japanese side

Chief Advisor, JICA Project Coordinator, and other JICA Experts

Representative(s) from JICA Kenya Office

Representative(s) from Embassy of Japan (Observer)

Representative(s) from JST (Observer)

-Other stakeholders appointed by the Chairperson

4-3. Project Steering Committee

A Project Steering Committee will be established and convened once every four (4) months. Its function and composition are as follows:

(1) Functions

1) To review progress and outputs of research activities,

2) To coordinate and exchange information; and

3) To discuss issues including technical, ethical, safety and any matters, arising from or concerning the Project.

(2) Composition

1) Chairpersons:

Director of CIPDCR-KEMRI (Alupe) or Director of KEMRI

2) Co-chairperson:

Chief Advisor

3) Members:

Research Team Leaders, KEMRI Researchers and MOPHS Personnel

JICA Project Coordinator

Other JICA Experts

4-4. Quarterly Progress Report

In order to ensure effective monitoring of the research progress and timely feedback of the technical advice from the experts, all team leaders engaged in the Project will report their quarterly activity and progress including administrative matters to the Project Director and the Chief Advisor via the Project Coordinator. The report will be prepared in English and will be

shared with the relevant researchers and personnel.

5. Contents of Collaborative Research

Both sides confirmed that the contents of collaborative research covered in the Project are as follows:

(1) Studies of Development of Rapid Diagnostics for Yellow Fever (YF) and Rift Valley Fever (RVF),

(2) Studies of Development of the Early Vigilance System for YF and RVF Outbreaks; and

(3) Other Relevant Studies.

6. Project Design Matrix and Tentative Plan of Operation

The basic framework of the Project is as shown in the PDM in Annex IV. The tentative PO is as shown in Annex V.

7. Inputs

The inputs from each side are as follows:

7-1. Japanese side

(1) Chief Advisor/Development of Rapid Diagnostics and Alert System,

(2) Project Coordinator,

(3) Other Experts in Research Management, Researchers, Genetic engineering, and Viral Experiments,

(4) Training in Japan for Virology (Recombinant Viral Protein Expression), Monoclonal Antibody Development, Laboratory Diagnosis, Quality Management System (QMS) for Production, Molecular Epidemiology and others,

(5) Necessary equipment for research and development activities, as shown in Annex VI,

(6) Necessary equipment and/or devices for development of the bidirectional early vigilance and rapid response mechanism, as shown in Annex VI; and

(7) Running expenses necessary for implementation of the project activities other than that borne by the Kenyan side.

7-2. Kenyan side

(1) Project Director,

(2) Project Manager,

(3) Project Co-managers,
(4) Researchers (Ph.D., MSc.) in Virology, Immunology, and Communicable Disease Surveillance
(5) Health Personnel engaged in Early Vigilance and Rapid Response for Outbreaks
(6) Office space at KEMRI headquarters and CIPDCR-KEMRI (Alupe)
(7) Laboratory space at KEMRI-Production Department (PD)
(8) BSL-3 laboratory at KEMRI
(9) BSL-2 laboratory at CIPDCR-KEMRI (Alupe)
(10) Clinical specimens from YF and RVF suspected cases
(11) Running expenses necessary for implementation of the project activities such as personnel costs of researchers, research activity costs including travel expenses, consumables, and supplies, utility costs such as water, electricity and communication, etc

8. Special Issues

8-1. Memorandum of Agreement between research institutes

Both sides agreed that NUITM and KEMRI should reach an agreement to execute the collaborative research in accordance with the project design. The document (e.g. Memorandum of Agreement) will contain the following items of the collaborative research:

a. Objective and Plan
b. Implementation
c. Confidentiality and Intellectual Property Rights
d. Access to Genetic Resources
e. Publication of Results
f. Dispute Resolution
g. Duration of the Agreement
h. Compliance with Laws and Regulations
i. Other items concerning both institutions

8-2. Intellectual Property Rights

Both sides confirmed that matters related to intellectual property rights should follow the Memorandum of Agreement to be signed between the two research institutes.

8-3. Exclusion of Clinical Trials

Both sides agreed that clinical trials will not be included in the Project.

JICA is indemnified for any and all liabilities, losses, and expenses on claims for injury or damages arising out of or resulting from the actions or omissions by NUITM and KEMRI, or of any of their officers, agents, employees, or subcontractors with respect to the clinical trials.

Therefore, JICA will not bear any expenses or honorarium for implementing clinical trials.

8-4.Ethical Approval of the Project

All research activities of the Project involving human subjects will be approved by the ethical committee of NUITM or KEMRI, as applicable.

8-5. Biosafety

In order to secure laboratories for research activities, both sides agreed that biosafety will be maintained according to laboratory biosafety regulations of relevant institutions.

8-6. Approval of Specific Activities

Both sides agreed that clearance of material transfer (import/export) from relevant ministry/authority should be obtained. The materials may include microbiological pathogens, human clinical specimens, animal materials, and so on.

8-7.Accreditation and Certification

Both sides noted that the Kenyan side should proceed with third-party accreditation in terms of quality evaluation of diagnostics by National Public Health Laboratory Services of MOPHS as well as ISO certification for KEMRI, necessary for official use of the rapid diagnostic test kits in Kenya.

III WAY FORWARD

1. Based on this M/M and the draft R/D as shown in Annex VII, the Kenyan and Japanese sides will prepare the final version of the R/D.
2. Before starting the Project, NUITM and KEMRI should take necessary

measures including the application to relevant ethical committees, and allocation of the budget.

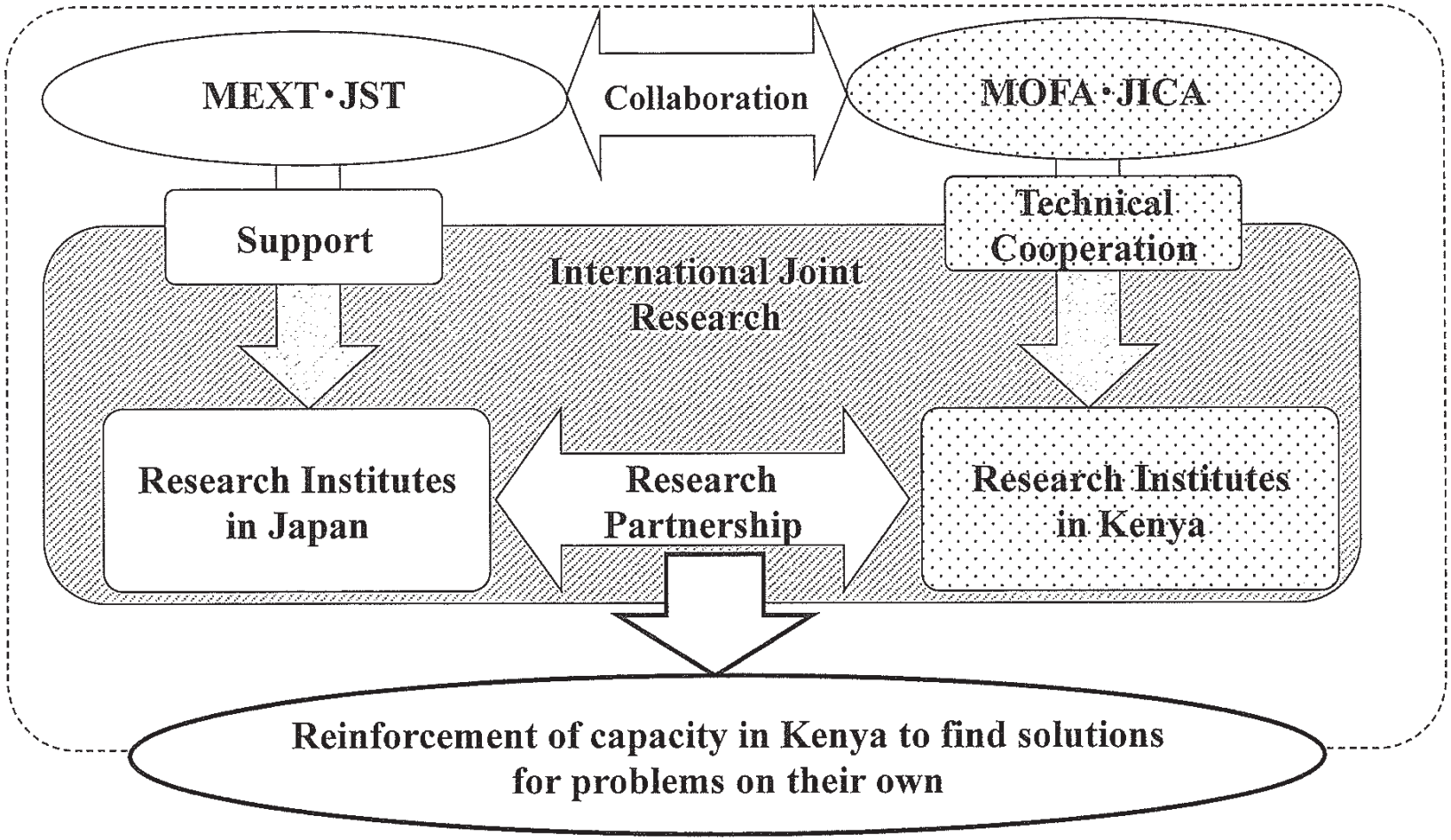
3. Based on the mutual agreement reached, the R/D will be signed by both sides by December 2011.
4. The Memorandum of Agreement between NUITM and KEMRI will be finalized after signing the R/D
5. The schedule is subject to change in accordance with approval processes of the Project.

LIST OF ANNEXES

Annex I	Project Implementation Scheme
Annex II	Project Implementation Structure
Annex III	Research Contents and researchers/Organizations in Charge
Annex IV	PDM Version 0
Annex V	Tentative PO Version 0
Annex VI	Tentative List of Equipment
Annex VII	Draft R/D

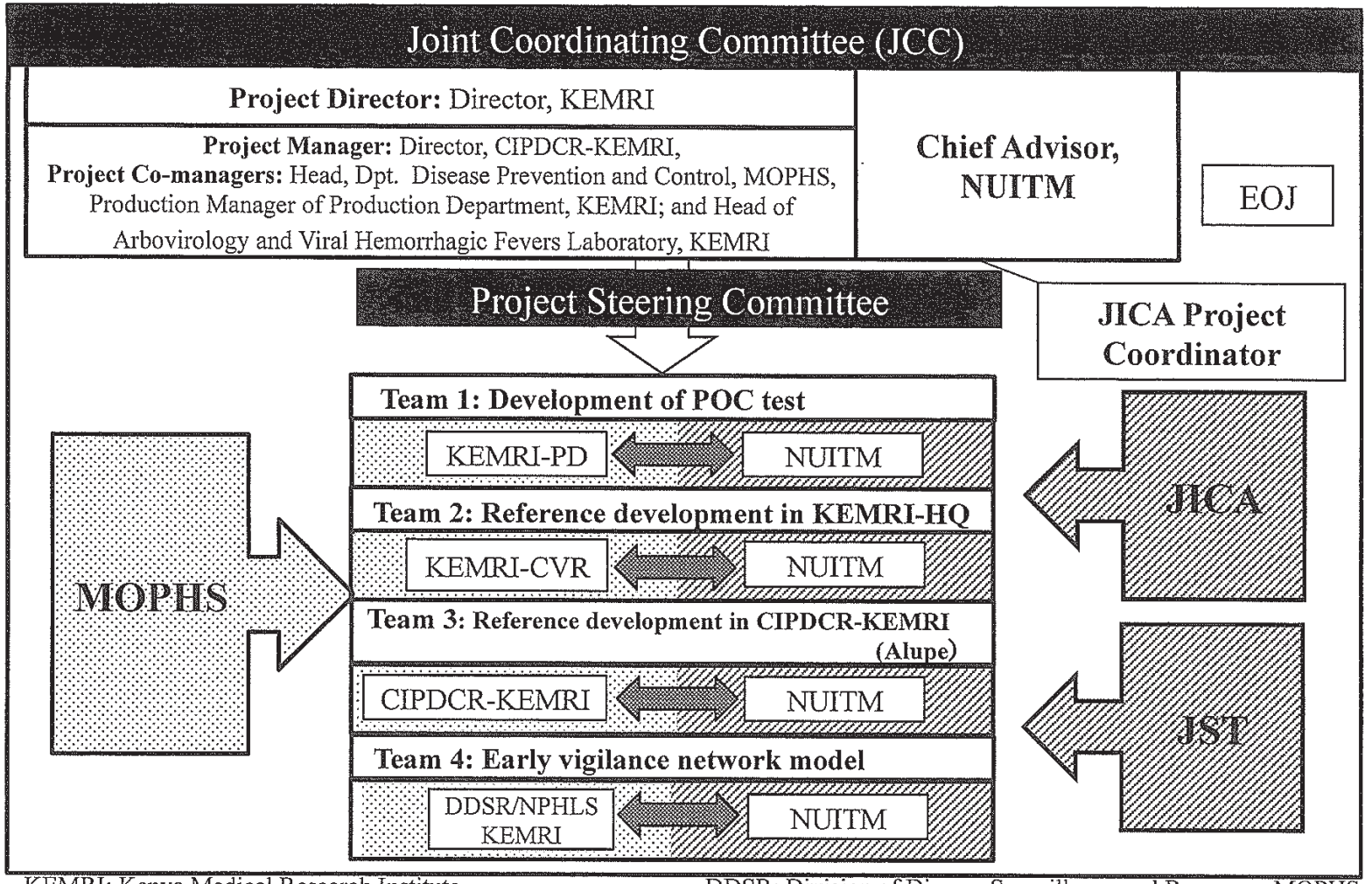
Annex I: Project Implementation Scheme

Science and Technology Research Partnership for Sustainable Development (SATREPS)



MEXT: Ministry of Education, Culture, Sports, Science and Technology
JST: Japan Science and Technology Agency
MOFA: Ministry of Foreign Affairs
JICA: Japan International Cooperation Agency

Annex II : Project Implementation Structure



KEMRI: Kenya Medical Research Institute
KEMRI-PD: Production Department, KEMRI
KEMRI-CVR: Centre for Virus Research, KEMRI
CIPDCR-KEMRI (Alupe):
Centre for Infectious and Parasitic Diseases Control Research, (Alupe) KEMRI

DDSR: Division of Disease Surveillance and Response, MOPHS
NPHLS: National Public Health Laboratory Services, MOPHS
NUITM: Nagasaki University, Institute of Tropical Medicine
EOJ: Embassy of Japan
MOPHS: Ministry of Public Health and Sanitation
POC test: Point-of-Care test

Annex III

Research Contents and Researchers Organizations in Charge

Japan	Supervise	Team 1	Team 2	Team 3	Team 4
		Development of POC test	Reference Development in KEMRI-HQ	Reference Development in CIPDCR-KEMRI (Alupe)	Early vigilance network model
Research Team Leaders	**Chief Advisor** Kouichi Morita NUITM Professor	Shingo Inoue NUITM Assistant Professor	Kouichi Morita NUITM Professor	Kouichi Morita NUITM Professor	Kouichi Morita NUITM Professor
		Researcher A NUITM Post Doc. Fellow	Shingo Inoue NUITM Assistant Professor	Shingo Inoue NUITM Assistant Professor	Shingo Inoue NUITM Assistant Professor
		Yu Fuxun NUITM Assistant Professor	Researcher A NUITM Post Doc. Fellow	Researcher A NUITM Post Doc. Fellow	Researcher A NUITM Post Doc. Fellow
		Yuki Takamatsu NUITM Student in Ph.D. course	Takeshi Nabeshima NUITM Assistant Professor	Takeshi Nabeshima NUITM Assistant Professor	
		Reo Uchida NUITM Student in Ph.D. course		Yuki Takamatsu NUITM Student in Ph.D. course	
				Reo Uchida NUITM Student in Ph.D. course	

Kenya	Supervise	Team 1	Team 2	Team 3	Team 4
		Development of POC test	Reference Development in KEMRI-HQ	Reference Development in CIPDCR-KEMRI (Alupe)	Early vigilance network model
Research Team Leaders	**Project Director** KEMRI-HQ Director	KEMRI-PD Production Manager	KEMRI-CVR Chief Research Officer	CIPDCR-KEMRI (Alupe) Director, Chief Research Officer	CIPDCR-KEMRI (Alupe) Director, Chief Research Officer
	Project Manager CIPDCR-KEMRI (Alupe) Director, Chief Research Officer	KEMRI-PD Chief Technologist	KEMRI-CVR Senior Research Officer	CIPDCR-KEMRI (Alupe) Senior Research Officer	Department of Disease Prevention and Control, MOPHS Department Head
		JKUAT Student in Ph.D. course	KEMRI-CVR Research Officer	CIPDCR-KEMRI (Alupe) Assistant Research Officer	Division of Disease Surveillance and Response, DDPC, MOPHS Division Head
		KEMRI-PD Technician	KEMRI-Workshop Chief Engineer Electrician	CIPDCR-KEMRI (Alupe) Assistant Research Officer	National Public Health Laboratory Services, MOPHS Division Head
		KEMRI-PD Technologist	KEMRI-Workshop Engineer Biosafety Cabinet	CIPDCR-KEMRI (Alupe) Assistant Research Officer	Epidemic Preparedness & Response Unit, DDSR, MOPHS Unit Chief
		KEMRI-PD Technologist		JKUAT Student in Ph.D. course	Integrated Disease & Surveillance Unit, DDSR, MOPHS Staff
				JKUAT Student in MSc. course	

Annex IV

Project Design Matrix (PDM) (Version 0)

Date: September 2, 2011

Project Title: Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arboviruses in Kenya
(Proposed Project Title by Japanese Side: The Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya)

Project Duration: *5* years from the date of first dispatch of Expert(s)

Target Area :Endemic areas of priority arbovirus infection in Central, Coast, Nairobi, North Eastern, and Western Provinces, the Republic of Kenya

Target Group :

Project Implementers: Approx. 200 researchers and health personnel engaged in early vigilance and rapid response for outbreaks of Yellow Fever (YF) and Rift Valley Fever (RVF).

【Kenya Medical Research Institute (KEMRI)】 Researchers: Production Department (PD), Centre for Virus Research (CVR), Centre for Infectious and Parasitic Diseases Control Research (CIPDCR) (Alupe)

【Ministry of Public Health and Sanitation (MOPHS)】 Health Personnel engaged in early vigilance and rapid response for outbreaks

Beneficiaries: Residents at risk for arbovirus Infection in Kenya: Central Province: Approx. 3.9 millions, Coast Province: Approx. 3million, Nairobi Province: Approx. 2.8 million, North Eastern Province: Approx. 1.3 millions, Western Province: Approx. 4million

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumptions
Project Purpose			
Outbreak containment system of YF and RVF is strengthened in Kenya through the development of rapid diagnostics and establishment of a sustainable outbreak vigilance and response mechanism.	1. Rapid diagnostic test kits for YF and RVF are stably available in the target area. 2. The Operational Manual is integrated into the national surveillance and response system for priority diseases by the MOPHS by the end of project period. 3. The time taken from the first clinical suspicious cases to confirmation of diagnosis is 1 week or less.	(1) Experts' project reports (2) Steering committee meeting minutes (3) Monthly progress reports (4) Integrated Disease Surveillance and Response (IDSR) Technical Guidelines	
Outputs			
1 **Rapid diagnostics (test kits) for YF and RVF are developed in collaboration between researchers in Kenyan and Japanese sides.**	1-1. Rapid diagnostic test kits and ELISA test kits using viral antigens with more than 90% sensitivity and specificity are produced in KEMRI by the end of 2013. 1-2. Rapid diagnostic test kits using genetically engineered antigens with more than 90% sensitivity and specificity are produced in KEMRI by the end of 2014. 1-3. KEMRI-PD receives the qualification of ISO 13485: 2003 by the end of 2014.	(1) Experts' project reports (2) Steering committee meeting minutes (3) Monthly progress reports (4) ISO 13485: 2003 certificate for KEMRI-PD	1. Kenyan side properly proceeds with third-party accreditation, in terms of quality evaluation of diagnostics by National public Health Laboratory Services (NPHLS) as well as ISO certification for KEMRI, necessary for official use of the rapid diagnostic test kits in Kenya. 2. Cooperation from relevant authorities for official authorization of the Operational Manual as a part of the national communicable diseases response system is gained.
2 **Advanced rapid and accurate reference activities are in place and functional in KEMRI headquarters as well as CIPDCR-KEMRI (Alupe) in collaboration between Kenyan and Japanese sides.**	2-1. Entire KEMRI receives the qualification of ISO 9001: 2008 by the end of 2012. 2-2. Sensitivity and specificity of laboratory diagnosis by ELISA and gene amplification technique in KEMRI are as same level as that in WHO collaborating centers by the end of 2014.	(1) Experts' project reports (2) Steering committee meeting minutes (3) Monthly progress reports (4) ISO 9001: 2008 certificate for KEMRI	
3 **Bidirectional early vigilance and rapid response mechanism model for YF and RVF outbreaks is established and evaluated in collaboration with MOPHS officials, selected health facilities officials and JICA Experts.**	3-1. Sensitivity/specificity, completeness and timeliness of reporting are improved in comparison to the baseline data. (*target values will be determined on the basis of baseline investigation by the Joint Coordinating Committee meeting in 2014*) 3-2. Results from POC testing for YF and RVF are reflected in the DDSR Weekly Bulletin by the end of 2015. *3-3. Indicators for the measurement of spreading rate of communicable diseases and its responses will be determined by the Joint Coordinating Committee meeting in 2014.* 3-4 Ratios of laboratory confirmed cases of YF and RVF reach 80% among all the suspicious cases in the target areas of the Project by the end of 2016. 3-5. The Operational Manual is officially authorized by the MOPHS by the end of 2016.	(1) Experts' project reports (2) Steering committee meeting minutes (3) Monthly progress reports (4) DDSR Weekly Bulletin (5) Document(s) for authorization of the Operational Manual	

Activities	Inputs		
	Japan	Kenya	
1 **Rapid diagnostics (test kits) for YF and RVF are developed in collaboration between researchers in Kenyan and Japanese sides.**	Experts (1) Chief Advisor/Development of Rapid Diagnostics and Alert System (Short-term experts) (2) Research Management (Long-term expert) (3) Researchers (Long-term expert) (4) Project Coordinator (Long-term expert) (5) Genetic Engineering (Short-term experts) (6) Viral Experiments (Short-term experts), etc. Training in Japan (1) Virology (Recombinant viral protein expression) (2) Monoclonal Antibody Development (4) Quality Management System (QMS) for Production (5) Molecular Epidemiology (6) Other necessary training Equipment and materials (1) Necessary equipment for research and development activities in the Project (2) Necessary equipment and/or devices for development of the bidirectional early vigilance and rapid response mechanism. Local costs Running expenses necessary for implementation of the project activities other than those that borne by the Kenyan side.	Counterparts (1) Project Director (2) Project Manager (3) Project Co-managers (4) Researchers (PhD, MSc) in Virology, Immunology, and Communicable Disease Surveillance. (5) Health Personnel engaged in Early Vigilance and Rapid Response for Outbreaks Land, Facilities, equipment and materials (1) Office space at KEMRI headquarters and CIPDCR-KEMRI (Alupe) (2) Laboratory space at KEMRI-PD (3) BSL-3 laboratory at KEMRI (4) BSL-2 laboratory at CIPDCR-KEMRI (Alupe) (5) Clinical specimens from YF and RVF suspected cases Local costs Running expenses necessary for implementation of the project activities such as personnel costs of researchers, research activity costs including travel expenses, consumables, and supplies, utility costs such as water, electricity and communication, etc.	1. Kenyan side allocates an adequate budget and personnel for the project activities. 2. Trained counterparts do not leave their position so as to affect the outputs of the Project. 3. Necessary cooperation is gained by health facilities and relevant agencies for the project activities.
1-1. Preparation of reference antigens of YF and RVF by large-scale cell culture systems.			
1-1-1. Establish a large-scale viral antigen preparation system using eukaryotic cells in KEMRI-PD.			
1-1-2. Prepare viral antigens by purifying virus particles from the system.			
1-2. Preparation of genetically-engineered antigens of YF virus and RVF virus for development of antibody-detecting rapid diagnostic test kit.			
1-2-1. Establish a large-scale expression system of viral protein antigens with cultured prokaryotic cells in KEMRI-PD.			
1-2-2. Prepare genetically-engineered diagnostic antigens, designed on the basis of preliminary study, by affinity chromatography technique.			
1-3. Production of conjugated monoclonal and polyclonal anti YF virus and RVF virus antibodies.			
1-3-1. Purify polyclonal antibodies from sera of experimental animals sensitized by YF and RVF viral antigens prepared by activity 1-1.			
1-3-2. Prepare monoclonal antibodies from large scale culture of hybridoma cells provided from the Institute of Tropical Medicine, Nagasaki University.			
1-3-3. Label polyclonal and monoclonal antibody by conjugating with Horseradish Peroxidase (HRP) or colloidal gold particles.			
1-4. Production of rapid diagnostic test kits for point-of-care (POC) testing of YF and RVF using immunochromatography technology.			
1-4-1. Coat each antigen on immunochromatography membrane using spraying machine.			
1-4-2. Fabricate rapid diagnostic test kits by assembling relevant parts produced in KEMRI-PD.			
1-4-3. Evaluate specificity, sensitivity and stability of the YF- and the RVF-rapid diagnostic test kits by comparative reviewing with advanced reference diagnostics of ELISA (Enzyme-Linked Immunosorbent Assay).			
1-4-4. Validate the rapid diagnostic test kits for POC testing at field level, developed by the Production Department, using clinical specimens at KEMRI-CVR and CIPDCR-KEMRI (Alupe).			
1-5. Preparation of ELISA tests for YF and RVF as higher reference diagnostics.			
1-5-1. Fabricate ELISA test kits by assembling relevant parts produced in KEMRI-PD.			

	1-5-2.	Validate the ELISA kits, developed by the Production Department, by using clinical specimens at KEMRI-CVR and CIPDCR-KEMRI (Alupe).
2	**Advanced rapid and accurate reference activities are in place and functional in KEMRI headquarters as well as CIPDCR-KEMRI (Alupe) in collaboration between Kenyan and Japanese sides.**	
2-1.	Strengthening reference capacity for rapid confirmation of YF and RVF at KEMRI headquarters.	
	2-1-1.	Enhance the function of existing Biosafety Level (BSL)-3 laboratory in the KEMRI headquarters by renovating it and supplying necessary research instruments.
	2-1-2.	Setup safe virus isolation system in BSL-3 laboratories targeting on YF virus and RVF virus for monitoring of antigenic variation and genetic mutation.
	2-1-3.	Set up and standardize gene amplification and detection system (e.g. real-time PCR) of YF virus and RVF virus as reference diagnostics at field laboratories.
	2-1-4.	Collect and analyze specimens for monitoring of antigenic variation and genetic mutation of YF virus and RVF virus.
2-2.	Establishment of primary reference capacity for confirmation of YF and RVF at CIPDCR-KEMRI (Alupe).	
	2-2-1.	Enhance the function of existing BSL-2 laboratory in CIPDCR-KEMRI (Alupe) by renovating it and supplying necessary research instruments.
	2-2-2.	Setup safe virus inoculation and RNA extraction system in the BSL-2 laboratory targeting on arboviruses.
	2-2-3.	Set up and standardize gene amplification and detection system at field laboratory level (e.g. real-time LAMP, conventional PCR).
	2-2-4.	Collect and analyze clinical specimens for diagnosis YF and RVF at field laboratory level.
3	**Bidirectional early vigilance and rapid response mechanism model for YF and RVF outbreaks is established and evaluated in collaboration with MOPHS officials, selected health facilities officials and JICA Experts.**	
3-1.	Integration of YF and RVF outbreak response network model into the existing communicable diseases response system in MOPHS/DDSR (Division of Disease Surveillance and Response).	
	3-1-1.	Set up a working group for development of YF and RVF outbreak response network model, composed of representatives from MOPHS, KEMRI, health facilities, other relevant agencies and Japanese experts.

	3-1-2. Develop a mobile networking system using verbal and Short Message Service (SMS) communication for communicable diseases vigilance and response system including YF and RVF.			
	3-1-3. Develop a draft Operational Manual of mobile phone-based bidirectional early vigilance and response for YF and RVF outbreaks.			
	3-1-4. Distribute mobile phones to health personnel engaged in communicable diseases outbreak vigilance and response system, followed by test operation of reporting system in accordance with the draft Operational Manual in a limited scale.			
3-2.	Set up the mobile phone linked network of selected health facilities and laboratories in Central, Coast, Nairobi, North Eastern, and Western, Provinces.			**Pre-conditions**
	3-2-1. Enroll 200 selected health facilities and laboratories in the pilot areas identifying a responsible personnel for each institution.			1. Approval is obtained by the Scientific Steering Committee (SSC) and the Ethical Review Committee (ERC) for the research subjects conducted in the Project.
	3-2-2. Provide trainings for manipulation of the rapid diagnostic test kits after its distribution to relevant facilities.			2. Approval is obtained from relevant ministry/authority for genetic engineering.
3-3.	Conduct outbreak report and response simulation including table-top exercises in collaboration with DDSR, KEMRI, selected health facilities and other relevant agencies.			3.Clearance for animal use is obtained from SSC, ERC and the Animal Care and Use Committee: ACUC of KEMRI.
3-4.	Verify the effectiveness of the novel outbreak vigilance and response system on spreading rate of communicable diseases and its responses by evaluating the data from the simulation in 3-3.			4. Clearance for material transfer or export/import is obtained from relevant ministry/authority.
3-5.	Revise and finalize the Operational Manual on the basis of the assessment results from the test operations and the simulations.			

【Abbreviations】 **JICA:** Japan International Cooperation Agency, **LAMP:** Loop-mediated Isothermal Amplification, **PCR:** Polymerase Chain Reaction, **RNA:** Ribonucleic Acid

Annex V Tentative Plan of Operation (PO) (Version 0)

Date: September 2, 2011

Project Title: Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arbovirus in Kenya
(Proposed Project Title by Japanese Side: The Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya)

Output 1:
Rapid diagnostics (test kits) for YF and RVF are developed in collaboration between researchers in Kenyan and Japanese sides.

Activities	Plan of Operation																					Institution in Charge		Remarks
	2012				2013				2014				2015				2016				2017	Japan	Kenya	
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan			
	2010 (J.F.Y.)	2011 (J.F.Y.)			2012 (J.F.Y.)				2013 (J.F.Y.)				2014 (J.F.Y.)				2015 (J.F.Y.)							
	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q			
1-1. Preparation of reference antigens of YF and RVF by large-scale cell culture systems.																								
1-1-1. Establish a large-scale viral antigen preparation system using eukaryotic cells in KEMRI-PD.																						NU	KEMRI-PD	
1-1-2. Prepare viral antigens by purifying virus particles from the system.																						NU	KEMRI-PD	
1-2. Preparation of genetically-engineered antigens of YF virus and RVF virus for development of antibody-detecting rapid diagnostic test kit.																								
1-2-1. Establish a large-scale expression system of viral protein antigens with cultured prokaryotic cells in KEMRI-PD.																						NU	KEMRI-PD	
1-2-2. Prepare genetically-engineered diagnostic antigens, designed on the basis of preliminary study, by affinity chromatography technique.																						NU	KEMRI-PD	
1-3. Production of conjugated monoclonal and polyclonal anti YF virus and RVF virus antibodies.																								
1-3-1. Purify polyclonal antibodies from sera of experimental animals sensitized by YF and RVF viral antigens prepared by activity 1-1.																						NU	KEMRI-PD	
1-3-2. Prepare monoclonal antibodies from large scale culture of hybridoma cells provided from the Institute of Tropical Medicine, Nagasaki University.																						NU	KEMRI-PD	
1-3-3. Label polyclonal and monoclonal antibody by conjugating with Horseradish Peroxidase (HRP) or colloidal gold particles.																						NU	KEMRI-PD	
1-4. Production of rapid diagnostic test kits for point-of-care (POC) testing of YF and RVF using immunochromatography technology.																								
1-4-1. Coat each antigen on immunochromatography membrane using spraying machine.																						NU	KEMRI-PD	
1-4-2. Fabricate rapid diagnostic test kits by assembling relevant parts produced in KEMRI-PD.																						NU	KEMRI-PD	
1-4-3. Evaluate specificity, sensitivity and stability of the YF- and the RVF-rapid diagnostic test kits by comparative reviewing with advanced reference diagnostics of ELISA (Enzyme-Linked Immunosorbent Assay).																						NU	KEMRI-PD KEMRI-CVR	
1-4-4. Validate the rapid diagnostic test kits for POC testing at field level, developed by the Production Department, using clinical specimens at KEMRI-CVR and CIPDCR-KEMRI (Alupe).																						NU	KEMRI-PD KEMRI-CVR CIPDCR-KEMRI (Alupe)	
1-5. Preparation of ELISA tests for YF and RVF as higher reference diagnostics.																								
1-5-1. Fabricate ELISA test kits by assembling relevant parts produced in KEMRI-PD.																						NU	KEMRI-PD	
1-5-2. Validate the ELISA kits, developed by the Production Department, by using clinical specimens at KEMRI-CVR and CIPDCR-KEMRI (Alupe).																						NU	KEMRI-PD KEMRI-CVR CIPDCR-KEMRI (Alupe)	

[Abbreviations] CIPDCR: Centre for Infectious and Parasitic Diseases Control Research (Alupe), CVR: Centre for Virus Research, J.F.Y.: Japanese Fiscal Year, NU: Nagasaki University, KEMRI: Kenya Medical Research Institute, PD: Production Department, RVF: Rift Valley Fever, YF: Yellow Fever

Annex V Tentative Plan of Operation (PO) (Version 0)

Date: September 2, 2011

Project Title: Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arbovirus in Kenya
(Proposed Project Title by Japanese Side: The Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya)

Output 2:
Advanced rapid and accurate reference activities are in place and functional in KEMRI headquarters as well as CIPDCR-KEMRI (Alupe) in collaboration between Kenyan and Japanese sides.

Activities	Plan of Operation																					Institution in Charge		Remarks
	2012				2013				2014				2015				2016				2017	Japan	Kenya	
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan			
	2010 (J.F.Y.)	2011 (J.F.Y.)				2012 (J.F.Y.)				2013 (J.F.Y.)				2014 (J.F.Y.)				2015 (J.F.Y.)						
	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q			
2-1. Strengthening reference capacity for rapid confirmation of YF and RVF at KEMRI headquarters.																								
2-1-1. Enhance the function of existing Biosafety Level (BSL)-3 laboratory in the KEMRI headquarters by renovating it and supplying necessary research instruments.	→	→	→	→																		NU	KEMRI-CVR	
2-1-2. Setup safe virus isolation system in BSL-3 laboratories targeting on YF virus and RVF virus for monitoring of antigenic variation and genetic mutation.			→	→	→	→	→															NU	KEMRI-CVR	
2-1-3. Set up and standardize gene amplification and detection system (e.g. real-time PCR) of YF virus and RVF virus as reference diagnostics at field laboratories.				→	→	→	→	→														NU	KEMRI-CVR	
2-1-4. Collect and analyze specimens for monitoring of antigenic variation and genetic mutation of YF virus and RVF virus.				→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	NU	KEMRI-CVR	
2-2. Establishment of primary reference capacity for confirmation of YF and RVF at CIPDCR-KEMRI (Alupe).																								
2-2-1. Enhance the function of existing BSL-2 laboratory in CIPDCR-KEMRI (Alupe) by renovating it and supplying necessary research instruments.	→	→	→	→	→																	NU	CIPDCR-KEMRI (Alupe)	
2-2-2. Setup safe virus inoculation and RNA extraction system in the BSL-2 laboratory targeting on arboviruses.				→	→	→																NU	CIPDCR-KEMRI (Alupe)	
2-2-3. Set up and standardize gene amplification and detection system at field laboratory level (e.g. real-time LAMP, conventional PCR).			→	→	→																	NU	CIPDCR-KEMRI (Alupe)	
2-2-4. Collect and analyze clinical specimens for diagnosis YF and RVF at field laboratory level.					→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	→	NU	CIPDCR-KEMRI (Alupe)	

[Abbreviations] CIPDCR: Centre for Infectious and Parasitic Diseases Control Research (Alupe), CVR: Centre for Virus Research, J.F.Y.: Japanese Fiscal Year, LAMP: Loop-mediated Isothermal Amplification, NU: Nagasaki University, KEMRI: Kenya Medical Research Institute, PCR: Polymerase Chain Reaction, PD: Production Department, RVF: Rift Valley Fever, YF: Yellow Fever

Annex V Tentative Plan of Operation (PO) (Version 0)

Date: September 2, 2011

Project Title: Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arbovirus in Kenya
(Proposed Project Title by Japanese Side: The Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya)

Output 3:
Bidirectional early vigilance and rapid response mechanism model for YF and RVF outbreaks is established and evaluated in collaboration with MOPHS officials, selected health facilities officials and JICA Experts.

Activities	Plan of Operation																					Institution in Charge		Remarks
	2012				2013				2014				2015				2016				2017	Japan	Kenya	
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan			
	2010 (J.F.Y.)	2011 (J.F.Y.)			2012 (J.F.Y.)				2013 (J.F.Y.)				2014 (J.F.Y.)				2015 (J.F.Y.)							
	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q			
3-1. Integration of YF and RVF outbreak response network model into the existing communicable diseases response system in MOPHS/DDSR (Division of Disease Surveillance and Response).																								
3-1-1. Set up a working group for development of YF and RVF outbreak response network model, composed of representatives from MOPHS, KEMRI, health facilities, other relevant agencies and Japanese experts.		→																				NU	MOPHS-DDSR KEMRI	NPHLS
3-1-2. Develop a mobile networking system using verbal and Short Message Service (SMS) communication for communicable diseases vigilance and response system including YF and RVF.			→																			NU	MOPHS-DDSR KEMRI	NPHLS
3-1-3. Develop a draft Operational Manual of mobile phone-based bidirectional early vigilance and response for YF and RVF outbreaks.			→	→																		NU	MOPHS-DDSR MOPHS-DVBD KEMRI	NPHLS
3-1-4. Distribute mobile phones to health personnel engaged in communicable diseases outbreak vigilance and response system, followed by test operation of reporting system in accordance with the draft Operational Manual in a limited scale.					→			→			→			→			→			→		NU	MOPHS-DDSR KEMRI	NPHLS
3-2. Set up the mobile phone linked network of selected health facilities and laboratories in Central, Coast, Nairobi, North Eastern, and Western, Provinces.																								
3-2-1. Enroll 200 selected health facilities and laboratories in the pilot areas identifying a responsible personnel for each institution.			→	→																		NU	MOPHS-DDSR KEMRI	NPHLS
3-2-2. Provide trainings for manipulation of the rapid diagnostic test kits after its distribution to relevant facilities.					→				→				→				→					NU	MOPHS-DDSR KEMRI	NPHLS
3-3. Conduct outbreak report and response simulation including table-top exercises in collaboration with DDSR, KEMRI, selected health facilities and other relevant agencies.						→				→				→				→				NU	MOPHS-DDSR KEMRI	NPHLS
3-4. Verify the effectiveness of the novel outbreak vigilance and response system on spreading rate of communicable diseases and its responses by evaluating the data from the simulation in 3-3.							→				→				→				→			NU	MOPHS-DDSR KEMRI	NPHLS
3-5. Revise and finalize the Operational Manual on the basis of the assessment results from the test operations and the simulations.								→				→				→				→		NU	MOPHS-DDSR MOPHS-DVBD KEMRI	NPHLS

[Abbreviations] CIPDCR: Centre for Infectious and Parasitic Diseases Control Research (Ahupe), CVR: Centre for Virus Research, DVBD:Division of Vector Borne Diseases, DDSR: Division of Disease Surveillance and Response, J.F.Y.: Japanese Fiscal Year, MOPHS: Ministry of Public Health and Sanitation, NPHLS: National Public Health Laboratory Services, MOPHS, NU: Nagasaki University, KEMRI: Kenya Medical Research Institute, PD: Production Department, RVF: Rift Valley Fever, YF: Yellow Fever

Annex VI

Tentative List of Equipment

Location	Item
DDSR	Mobile Phone
	Printer for SMS
KEMRI-PD	Vehicle
	Deep Freezer (-80°C)
	Freezer (-30°C)
	Autoclave
	Biosafety Cabinet
	Clean Bench
	Heat Sterilizer
	Immunochromatography Spraying Machine
	Lyophirizer
	Shaker Incubator
	Ordinary Incubator
	CO_2 Gas Incubator
	Slow-speed Anti-humid Stirrer
	Electric Sealer
	Rotor and Buckets (SW32Ti)
	Rotor and Buckets (SW55Ti)
	Personal Computer
	Printer for PC
	Thermal Cycler (Gradient Type)
	UV Trans-illuminator
	Gel Image Analyzer with PC
	Minigel Electrophoresis Set for DNA
	Gel Electrophoresis Set for Protein
	Two Dimension Gel Electrophoresis Set
	Blotting Machine
	Inverted Microscope
	Digital Camera with Adaptor Set
	Ultra-pure Water System
	DNA Analysis Software
	Crashed Ice Maker
	Low-speed Refrigerated Centrifuge
	High-speed Refrigerated Micro-centrifuge
	Desk-top Micro-centrifuge
	Large Capacity AVS
	Small Capacity AVS
	DNA Sequencer
	Apparatus for DNA Sequencer
	Spectrophotometer
	Air-conditioner for Materials Room

Location	Item
KEMRI-CVR	UPS for BSL-3 Lab. System
	HEPA Filters for Biosafety Cabinet
	HEPA Filters for BSL-3 Lab.
	Deep Freezer (-80°C) Small in BSL-3 lab.
	Deep Freezer (-80°C) Large in BSL-2 Lab.
	Real-time PCR Thermal Cycler
	Inverted Microscope

CIPDCR-KEMRI (Alupe)	Vehicle
	BSL-2 Laboratory System Unit
	Deep Freezer (-80°C)
	Racks forDeep Freezer (-80°C)
	Freezer (-30°C)
	Refrigerator (4°C)
	Autoclave
	Biosafety Cabinet
	Clean Bench
	Ordinary Incubator
	CO_2 Gas Incubator
	Large Capacity AVS
	Small Capacity AVS
	Personal Computer
	Printer for PC
	Thermal Cycler (Gradient Type)
	UV Trans-illuminator
	Gel Image Analyzer with PC
	Minigel Electrophoresis Set for DNA
	Inverted Microscope
	Stereo Microscope
	Digital Camera with Adaptor Set
	Water Deionization System
	Water Purification System (Distiller)
	Ultra-pure Water System
	Crashed Ice Maker
	Low-speed Ref. Centrifuge
	High-speed Ref. Micro-centrifuge
	Blood Counter
	Blood Chemical Analyzer
	Electrical Balance
	Electrical Chemical Balance
	Generator for BSL-2 Lab.
	Spectrophotometer
	Air-conditioner for BSL-2 Lab.
	Peristaltic Pump
	pH Meter

Annex VII

(Draft)
RECORD OF DISCUSSIONS

ON THE PROJECT

FOR

DEVELOPMENT OF RAPID DIAGNOSTICS AND THE ESTABLISHMENT OF AN ALERT SYSTEM FOR OUTBREAKS OF YELLOW FEVER AND RIFT VALLEY FEVER IN KENYA

AGREED UPON BETWEEN

MINISTRY OF PUBLIC HEALTH AND SANITATION

AND

JAPAN INTERNATIONAL COOPERATION AGENCY

[Nairobi], [date]

JICA Kenya Office	Ministry of Public Health and Sanitation

Countersigned by;

	Ministry of Finance

Witnessed by;

Nagasaki University	Kenya Medical Research Institute

Based on the minutes of meetings on the Detailed Planning Survey on the "Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arbovirus in Kenya" signed on September 2, 2011 among Ministry of Public Health and Sanitation (hereinafter referred to as "MOPHS"), Kenya Medical Research Institute (hereinafter referred to as "KEMRI"), Nagasaki University, Institute of Tropical Medicine (hereinafter referred to as "NUITM") and the Japan International Cooperation Agency (hereinafter referred to as "JICA"), JICA and MOPHS held a series of discussions with KEMRI, NUITM and other relevant organizations to develop the detailed plan and completed the diplomatic procedure for change of the project title to "the Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya" (hereinafter referred to as "the Project").

Both parties agreed to the details of the Project and the main points discussed as described in Appendix 1.

Both parties also agreed that MOPHS, the counterpart to JICA, will be responsible for the implementation of the Project in cooperation with JICA, coordinate with KEMRI, NUITM, and other relevant organizations and ensure that the self-reliant operation of the Project is sustained during and after the implementation period in order to contribute toward both social and economic development and national response through new technology to the global issues (e.g. borderless infectious diseases) of the Republic of Kenya.

The Project will be implemented within the framework of the Agreement on Technical Cooperation signed on 29th April 2004 and the Note Verbales exchanged on 24th August 2011 between the Government of Japan (hereinafter referred to as "GOJ") and the Government of the Republic of Kenya (hereinafter referred to as "GOK").

Appendix 1: Project Description

Appendix 2: Minutes of Meetings on the Detailed Planning Survey for

"Development of Rapid Diagnostic Test Kits in KEMRI and the Establishment of an Alert System for Outbreaks of Priority Arbovirus in Kenya"

PROJECT DESCRIPTION

Both parties confirmed that there is no change in the Project Description as agreed on in the Minutes of Meetings concerning the Detailed Planning Survey for the Project signed on September 2, 2011 (Appendix 2).

I. BACKGROUND

Outbreaks of arthropod-borne viral (arbovirus) infections such as Yellow Fever (YF) virus, Rift Valley Fever (RVF) virus, Chikungunya (CHIK) virus and Dengue (DEN) virus are periodically reported with high case fatality rate in Kenya and its neighboring countries.

It was reported that in all of these outbreaks, it took several days for diagnosis to be confirmed.

Based on this observation, it was hypothesized that if the rapid diagnostics (test kits) had been available at the right time, these outbreaks could have been prevented from spreading in Kenya and East Africa, while the rapid diagnostics (test kits) are commercially available only for CHIK and DEN virus.

In addition, an alert system network for early response to outbreaks of arbovirus infections is also required in order to report outbreaks of the diseases.

This project was requested to develop and produce rapid diagnostic test kits for YF virus and RVF virus at KEMRI Production Department (PD) in Nairobi, to build a field surveillance system at KEMRI-Centre for Infectious and Parasitic Diseases Control Research (CIPDCR) in Alupe, and to establish an early vigilance model against outbreaks of arbovirus infections in partnership with MOPHS.

II. OUTLINE OF THE PROJECT

Details of the Project are described in the Project Design Matrix (hereinafter referred to as "PDM") (Annex I) and the tentative Plan of Operation (hereinafter referred to as "PO") (Annex II).

1. Title of the Project

The Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya

2. Project Purpose

Outbreak containment system of YF and RVF is strengthened in Kenya through the development of rapid diagnostics and establishment of a sustainable outbreak vigilance and response mechanism

3. Outputs

(1) Rapid diagnostics (test kits) for YF and RVF are developed in collaboration between researchers in Kenyan and Japanese sides

(2) Advanced rapid and accurate reference activities are in place and functional in KEMRI headquarters as well as CIPDCR-KEMRI (Alupe) in collaboration between Kenyan and Japanese sides

(3) Bidirectional early vigilance and rapid response mechanism model for YF and RVF outbreaks is established and evaluated in collaboration with MOPHS officials, selected health facilities officials and JICA Experts.

4. Inputs

(1) Inputs by JICA and NUITM

(a) Dispatch of Experts

-Chief Advisor/Development of Rapid Diagnostics and Alert System
-Research Management
-Project Coordinator
-Researchers
-Genetic Engineering
-Viral Experiments

(b) Training in Japan

-Virology (Recombinant Viral Protein Expression)
-Monoclonal Antibody Development
-Laboratory Diagnosis
-Quality Management System (QMS) for Production
-Molecular Epidemiology
-Other necessary trainings.

(c) Machinery and Equipment

- Necessary equipment for research and development activities, as shown in Annex IV
- Necessary equipment and/or devices for development of the bidirectional early vigilance and rapid response mechanism, as shown in Annex IV

Inputs other than those indicated above will be determined through consultations among JICA, MOPHS, KEMRI, and NUITM during the implementation of the Project, as necessary.

(2) Inputs by MOPHS and KEMRI

MOPHS and KEMRI will take necessary measures to provide at their own expense:

(a) Services of MOPHS's counterpart personnel, and KEMRI's counterpart researchers as referred to in II-5 (1),
(b) Suitable office, laboratory and research space with necessary equipment,
(c) Supply or replacement of machinery, equipment, instruments, vehicles, tools, spare parts and any other materials necessary for the implementation of the Project other than the equipment provided by JICA,
(d) Available data, clinical specimens and information related to the Project,
(e) Running expenses necessary for the implementation of the Project; and
(f) Expenses necessary for transportation within Kenya of the equipment referred to in II-4 (1) as well as for the installation, operation and maintenance thereof.

5. Implementation Structure

The Project Implementation Structure is shown in Annex III. The roles and assignments of both sides are as follows.

(1) Kenyan side will assign:

(a) Project Director (who will bear overall responsibility for the administration and implementation of the Project): Director, KEMRI headquarters,
(b) Project Manager (who will be responsible for the managerial and

technical matters of the Project): Director, CIPDCR-KEMRI (Alupe),

(c) Project Co-managers (who will be responsible for the managerial and technical matters of the Project, in collaboration with the Project Manager): Director of Department of Diseases Prevention and Control, MOPHS, Production Manager of Production Department, KEMRI; and Head of Arbovirology and Viral Hemorrhagic Fevers Laboratory, KEMRI.

(d) KEMRI counterpart researchers; and

(e) MOPHS counterpart personnel.

(2) Japanese side will dispatch:

(a) Chief Advisor (who will provide necessary recommendations and advice to the Project Director and the Project Manager and the Project Co-managers on any matters pertaining to the implementation of the Project),

(b) JICA Project Coordinator (who will coordinate the Project, supporting the Chief Advisor); and

(c) Other JICA experts (who will give necessary technical guidance and advice to KEMRI counterpart researchers and MOPHS personnel on technical matters pertaining to the implementation of the Project).

(3) Joint Coordinating Committee

A Joint Coordinating Committee (hereinafter referred to as "JCC") will be established in order to facilitate inter-organizational coordination. JCC meeting will be held at least once a year and whenever deemed necessary. JCC will approve the annual work plan, review overall progress, conduct monitoring and evaluation of the Project, and exchange opinions on major issues that arise during the implementation of the Project. A list of proposed members of JCC is shown in Annex V.

6. Project Target Area, Implementers and Beneficiaries

Project Target Area: Endemic areas of priority arbovirus infectious diseases in Kenya

Project Implementers: Approximately 200 researchers and health personnel engaged in early vigilance and rapid response for outbreaks of YF and RVF composed of Researchers from Production Department (PD), Centre for Virus Research (CVR), Centre for Infectious and Parasitic Diseases

Control Research (CIPDCR) (Alupe) of KEMRI and health personnel engaged in early vigilance and rapid response for outbreaks of MOPHS

Beneficiaries: Residents at risk for arbovirus Infection in Kenya: Central Province: Approx. 3.9 millions, Coast Province: Approx. 3million, Nairobi Province: Approx. 2.8 million, North Eastern Province: Approx. 1.3 millions, Western Province: Approx. 4million.

7. Duration

The duration of the technical cooperation for the Project will be five (5) years from the date of the first dispatch of Experts.

8. Reports

JICA, MOPHS, KEMRI, and NUITM will jointly prepare the following reports in English.

(1) Progress Report on semiannual basis until the project completion; and

(2) Project Completion Report at the time of project completion.

9. Environmental and Social Considerations

MOPHS, KEMRI, and NUITM agreed to abide by 'JICA Guidelines for Environmental and Social Considerations' in order to ensure that appropriate considerations will be made for the environmental and social impacts of the Project.

III. UNDERTAKINGS OF MOPHS

1. MOPHS will take necessary measures to:

(1) Ensure that the technologies and knowledge acquired by the Kenyan nationals as a result of Japanese technical cooperation contributes toward both economic and social development and national response through new technology to the global issues (e.g. borderless infectious diseases) of Kenya, and that the knowledge and experience acquired by the personnel of Kenya from technical training as well as the equipment provided by JICA will be utilized effectively in the implementation of the Project; and

(2) Grant privileges, exemptions and benefits to the JICA experts referred to in II-4 (1) above and their families, which are no less favorable than those

granted to experts and members of the missions and their families of third countries or international organizations performing similar missions in Kenya.

2. Other privileges, exemptions and benefits will be provided in accordance with the Agreement on Technical Cooperation signed on 29th April, 2004 between the GOJ and the GOK.

IV. EVALUATION

JICA, MOPHS, KEMRI and NUITM will jointly conduct the following reviews and evaluations :

1. Mid-term review at the middle of the cooperation term based on the Ex-ante Evaluation Sheet, as is shown in the Annex VI; and
2. Terminal evaluation at least the last six (6) months before the end of the cooperation term.

JICA, on its part, will conduct the following evaluations and surveys to mainly verify sustainability and impact of the Project and draw lessons. KEMRI is required to provide necessary support for these activities:

1. Ex-post evaluation three (3) years after the project completion, in principle; and
2. Follow-up surveys on necessity basis.

V. PROMOTION OF PUBLIC SUPPORT

For the purpose of promoting support for the Project, MOPHS and KEMRI will take appropriate measures to make the Project widely known to the people of Kenya.

VI. CONSULTATION

JICA MOPHS, KEMRI, and NUITM will consult one another whenever any major issues arise in the course of Project implementation.

VII. AMENDMENTS

The Record of Discussions may be amended by the minutes of meetings between Japanese and Kenyan sides.

The minutes of meetings will be signed by authorized representatives of each side who may be different from the signatories to the Record of Discussions.

Annex I	PDM (MM Annex IV)
Annex II	Tentative PO (MM Annex V)
Annex III	Project Implementation Structure(MM Annex I)
Annex IV	Tentative List of Equipment (MM Annex VI)
Annex V	List of Proposed Members of Joint Coordinating Committee/ Project Steering Committee
Annex VI	Ex-ante Evaluation Sheet (To be decided)

ANNEX IV Joint Coordinating Committee

For the effective and successful implementation of technical cooperation for the Project, a Joint Coordinating Committee will be established whose functions and composition are described as follows:

(1) Functions

1) To formulate and authorize the annual activity plan of the Project,

2) To endorse major achievements and products of the Project,

3) To monitor and review overall progress and supervise the Project; and

4) To review and discuss on major issues arising from or concerning the Project.

(2) Composition

1) Chairperson: Project Director

2) Members:

-Kenyan side

Project Manager, Project Co-managers

KEMRI counterpart researchers

MOPHS counterpart personnel

-Japanese side

Chief Advisor, JICA Project Coordinator, and other JICA Experts

Representative(s) from JICA Kenya Office

Representative(s) from Embassy of Japan (Observer)

Representative(s) from JST (Observer)

-Other stakeholders appointed by the Chairperson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