In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR APPLICATIONS FOR IMPORT AND EXPORT OF BIOLOGICAL SAMPLES

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TABLE OF CONTENTS

1. PURPOSE

The purpose of this SOP is to describe processes that are involved in samples/specimen import export and storage.

2. SCOPE

This SOP covers requirements and process of samples export, import and storage. It does not cover local transportation of samples from one local institution/laboratory to another.

3. INTRODUCTION

During study conduct samples are generated. Some of the samples generated may require tests that are not available in-country or there may be need to make comparison of results. There is need to have in place a plan and procedure of handling matters that may arise pertaining to samples export, import and storage.

KEMRI collaborates with numerous research scientists, research organizations, and academic institutions throughout the world. Many a times local scientists or collaborating scientists from other countries request for exportation or storage of human blood and other biological samples for research purposes. However, no clear guidelines are currently in place in the Institute to regulate this process, and to fully safeguard the interests and rights of study subjects and the Kenyan public in general. Guidelines are designed for the purpose of regulating exportation and storage of human blood samples and other biological materials, and safeguarding the Kenyan public against experimentation without their consent or approval of the Institute.

4. TERMS & DEFINITIONS

Refer to SERU Glossary

5. OBJECTIVES

To ensure biological samples are exported and imported with relevant permits.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails
6.4 Phone

7. EXPECTED OUTPUTS

7.1 Processed shipment document
7.2 Record of applications received

8. KEY PERFORMANCE INDICATORS

8.1 No. of shipments approved
8.2 No. of shipments declined

9. RESPONSIBILITY AND AUTHORITY

Investigator-It is the responsibility of the PI to ensure that any sample export or import done is authorised by the relevant authorities as stipulated in KEMRI

10. DETAILS OF PROCEDURE

10.1 If extended storage of samples (beyond the duration of the approved period of the research study) is anticipated, the Principal Investigator (PI) of the study must state so in the research proposal, and when completing the shipment request form, he or she has to indicate the exact location of sample storage, duration of storage (for a specific period), and reasons for storage. If multiple shipments of samples out of the country are anticipated, a separate request and approval will be needed for each shipment.

10.2 All the investigations/analyses to be performed on human blood or other biological materials in the country receiving the specimens should be stated both in the proposal (or its amended version), and in the exportation/storage request form. The PI or the other investigators in the study must provide reasons why these tests cannot be done locally in Kenya, and what is being done to transfer the necessary technology to Kenya.

10.3 If the P.I had not included the details of the sample recipients e.g. collaborators or commercial institutions at the initial submission of the protocol, he/she should amend the protocol and consent forms to include this information once it is available, and prior to the shipment of samples

10.4 In the event that further studies (other than those stated in the research protocol) are proposed on the stored or exported samples, approval must be sought from KEMRI, through its Scientific and Ethics Review Unit (SERU).

10.5 All shipment applications for KEMRI-based studies shall be submitted by the PI to the office of the SERU Secretariat.

10.6 A complete application shall include the following items:

10.6.1 A duly signed explanatory cover letter.

10.6.2 One duly completed Request for Shipment Form. (Appendix I)

10.6.3 Where applicable, one copy of the initial and current SSC and ERC approval letter for the study.

10.6.4 Where applicable, one copy of the initial and current SERU approval letter for the study.

10.6.5 One copy of the initial and current Pharmacy and Poison's Board (PPB) approval letter for all clinical trials

10.6.6 One copy of the Approved Consent Documents indicating provisions to consent participants for sample exportation, storage and future research

10.6.7 The section(s) of the approved protocol which justifies the need for shipment of samples

10.7 Upon receipt of a shipment application from the Centre Director, the SERU Secretariat shall ensure that the application is reviewed within three (3) working days of receipt.

10.8 The SERU Secretariat shall review the application to ensure that:

10.8.1 A detailed description of the quantity and type of sample/specimen has been provided (e.g. 100 vials each containing 100 microlitres of serum, 100 vials of P. falciparum isolates, 2 boxes each containing 200 buccal swabs).

10.8.2 The number, type and dimension of tissue blocks to be exported are explicitly defined.

10.8.3 Any planned storage of the samples is not beyond the specified period of analysis in the study protocol or beyond the approved study period. Permission must be sought from the Head SERU and the Deputy Director for Research and Development (DDRD) for the use of the specified samples/specimens each time the period of analysis exceeds twelve (12) months or the prescribed study approval period.

10.8.4 There is/was provision for the participant to consent to storage, export and future use of sample or specimen in the approved Informed Consent Form and in the approved study protocol.

10.8.5 The study protocol and consent and/or assent documents specified that the samples/specimens in question would be shipped to a particular destination for the purpose(s) described.

10.8.6 There are no plans for long-term storage of the samples overseas. Any prolonged storage of biological samples is local and only in one of the KEMRI Research Centres. Consideration shall be made for multi-centre studies which require that a repository be formed at a coordinating centre outside Kenya. In such cases, the SERU shall require that a similar repository be held at a KEMRI research facility. The samples/specimens at the overseas coordinating centre must be destroyed within one (1) month of completion of the study. A memorandum of destruction of the biological samples or specimens must be submitted to the SERU within three (3) working days of the event.

10.9 Once the shipment request has been approved by the Head, SERU, it shall be forwarded in writing to the Deputy Director for Research and Development (DDRD) for final approval within five (05) working days of receipt.

10.10 Once the final authority to export the biological sample/specimen has been issued by the Deputy Director Research and Development, the SERU Secretariat staff shall make one file copy of the application then forward the approved application to the PI via the respective Centre Director within twenty four (24) hours of receipt of the document.

10.11 The approved shipment application allows for the shipment of the specified samples only and is valid for 90 calendar days. The use of a permit for unspecified samples is strictly prohibited.

10.12 Any applications which do not meet the conditions set out in Clause 24.2 and Clause 24.5 shall not be processed.

10.13 The SERU Secretariat shall write a letter to the PI explaining the basis for the deferral of the application. The letter shall be dispatched within three (3) working days of receipt of the application.

10.14 If the approval expires before the actual shipment is done, the PI shall be required to complete a new application form; attach the expired form and provide a cover letter detailing the reasons for the delay. The request shall be processed expeditiously provided that the contents of the re-submission remain unaltered.

10.15 The authority to ship biological samples or specimens from non-KEMRI affiliated studies (NON-SSC/NON KEMRI category) should be obtained from the Head of the Department of

Standards and Regulatory Services (DSRS), Ministry of Health, Afya House, Cathedral Road. P. O. Box 30016-00100, Nairobi, Kenya. Telephone number: + 254 20 2717077 FAX: + 254 20 2722986.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Application for import and export of biological samples	Delay in shipment approval	Delay in approval by Management	Apply the shipment permit early

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Application for import and export of biological samples	To acquire good equipment for storage of samples while awaiting approval.	Seek for funding or do a budget for the requisition of the equipment

12. REFERENCE DOCUMENTS

12.1 None

13. ANNEXES

13.1 SERU FORM FOR EXPORTATION OF SAMPLES

13.2 Flow chart Procedures.

ANNEX 1: SERU FORM FOR EXPORTATION OF SAMPLES

APPENDIX I_SERU FORM FOR EXPORTATION OF SAMPLES

GUIDELINES FOR EXPORTATION AND STORAGE OF HUMAN BLOOD AND OTHER BIOLOGICAL SAMPLES FOR RESEARCH

I. PREAMBLE:

KEMRI (herein referred to as the "Institute") collaborates with numerous research scientists, research organizations, and academic institutions throughout the world. Many a times local scientists or collaborating scientists from other countries request for exportation or storage of human blood and other biological samples for research purposes.

However, no clear guidelines are currently in place in the Institute to regulate this process, and to fully safeguard the interests and rights of study subjects and the Kenyan public in general. The following guidelines are designed for the purpose of regulating exportation and storage of human blood samples and other biological materials, and safeguarding the Kenyan public against experimentation without their consent or approval of the Institute.

II. CHECKLIST FOR SHIPMENT APPLICATIONS

A complete application shall include the following items:

1. A duly signed explanatory cover letter.
2. One duly completed and signed Form SERU XXXX.
3. One copy of the initial and current SERU approval letter for the study.
4. One copy of the initial and current PPB approval letter for all clinical trials.
5. One copy of the Approved Consent Documents
6. The section (s) of the approved protocol which justifies the need for shipment of samples.

III. GUIDELINES:

1. No human blood or other biological materials may be taken out of Kenya by an individual or groups of individuals working in or with the Institute, without the permission and approval of the Director KEMRI, on the advice of the Scientific and Ethics Review Unit (SERU).

2. Investigators anticipating to store (for an extended period beyond study duration) or to take human blood and other biological materials out of the country for further research or analysis, have to state so in their research proposals. If multiple shipment of samples out of the country is anticipated, a separate request and approval will be needed for each shipment. All requests for sample storage or exportation will be made on Form SERU 1/91d of the SERU, when need arises.

3. In the case of studies involving human subjects, the study subjects **MUST** have consented to exportation or storage of samples taken from them, and this must be reflected in the consent seeking and study explanation documents of the research protocol. Study participants have the right to refuse specimen storage or exportation.

4. In the event that an investigator needs to store or export specimens obtained from human subjects, and consent for this was never obtained, approval must be sought from the SERU.

5. If extended storage of samples (beyond the duration of the current study) is anticipated, the Principal Investigator (PI) of the study must state so in the research proposal, and when completing the request form, he or she has to indicate the location of sample storage, duration of storage (e.g. indefinitely or for a specific period), and reasons for storage.

6. In the event that further studies (other than those stated in the research protocol) are proposed on the stored or exported samples, approval must be sought from KEMRI, through its Scientific and Ethics Review Unit (SERU).

7. All the investigations/analyses to be performed on human blood or other biological materials in the country receiving the specimens should be stated both in the proposal (or its amended version), and in the exportation/storage request form. The PI or the other investigators in the study must provide reasons why these tests cannot be done locally in Kenya, and what is being done to transfer the technology to perform the tests to Kenya.

8. In the case of sample exportation, the recipient institution/department (i.e. where the human blood or other biological materials will be sent to) should be indicated in the proposal and in the request form, and the Head of the Institution/ Department will sign a declaration, accepting responsibility and control over usage of these samples.

9. The name(s) of the individual(s) responsible for the transportation/storage of the blood or other biological samples, and the tests to be performed on the samples in the country of destination should be indicated in the request form. A Kenyan investigator should be included in the team to undertake the proposed or planned investigations/analyses in the recipient country, as part of human resource development and technology transfer. If a Kenyan investigator is not involved, an explanation must be provided.

10. The PI or investigators requesting approval to export or store human blood and/or other biological specimens **must** undertake to declare the results of their

investigations/analysis to the Institute, and ensure that any publications arising from the studies will acknowledge the involvement and contributions of the Institute, and in the case of publications, the approval of the Director KEMRI to publish the research findings.

11. The PI(s) will ensure that the interests and intellectual property rights of the Institute or Kenyan investigators with respect to work performed on the stored or exported samples or related research, are safe-guarded.

Form SERU 7/14

KENYA MEDICAL RESEARCH INSTITUTE

SCIENTIFIC AND ETHICS REVIEW UNIT (SERU)

REQUEST FOR EXPORTATION OR STORAGE OF HUMAN SAMPLES AND OTHER BIOLOGICAL MATERIALS FOR RESEARCH

PART A: Project Information

i. Project Title: ----------

---**SERU/SSC No**.----------

---

ii. KEMRI Centre of Affiliation: ----------

iii. Principal Investigator(s):

1. ----------

2. ----------

3. ----------

iv. Other Investigators:

1. ----------

2. ----------

3. ----------

4. ----------

5. ----------

PART B: Specimen Details:

i. Is the request for specimen exportation or storage or both?

--

(Request for storage is necessary if the samples are to be stored beyond the duration of the present study)

ii. Description of specimen(s) to be exported/ stored:

---

iii. Reason(s) for exportation/storage of samples:

1. ---

2. ---

3. ---

iv. Duration of specimen storage: ---

v. **For samples originating from human subjects, state whether or not written consent for specimens exportation or storage**:

---

vi. Name and address of recipient institution/department responsible for the specimens:

(If samples are to be sent to more than one institution/department, a separate request form should be completed for each recipient)

vii. Name(s) and address of person(s) responsible for the specimens in the recipient institution:

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vi. Name and role in the project of the Kenyan investigator(s) expected to carry out investigations on the specimens in the overseas institution:

PART C: Declarations: (To be completed every time prior to shipping samples)

i. Declaration by the person requesting exportation/storage of research specimens:

I certify that the information provided in this request form is true and correct to the best of my knowledge, and I hereby declare that the specimens referred to herein will be utilized for the stated purpose only

Name:- ---------- **Role in the Project**:----------

Signature: ---------- **Date**: ----------

---

ii. Declaration by Recipient Institution:

This is to certify that the specimens referred to herein being sent to ----------(Name of Institution) for further analyses/experimentation will be in the custody of the Department of ----------, and I hereby confirm that they will be utilized for the purpose stated in this request form, and I accept full responsibility and control over the usage of these samples

Name of Department/Institution Head: ----------

Signature: ---------- **Date**: ----------

---

iii. Declaration by Centre Director:

I certify that the protocol SERU/SSC No ---------- referred to in this request was approved by the Centre's Scientific Committee on ---------- and that the request to export the biological specimens referred to in this request was found to be valid and justifiable. I further confirm that the study participants in this project have consented in writing to the exportation/ storage of samples taken from them, for use in further research.

Name: ----------Signature: ----------

-

Centre: ---------- **Date**: ----------

PART D: (For SERU Use Only)

i. Request Approved by the SERU on ----------**Name of the Officer**----------

Sign----------

ii. Request Not Approved by the SERU on ----------**Name of the Officer**---------

Sign----------

iii. Request Considered and Deferred Due to the Following Reasons:

1) ----------

2) ----------

3) ----------

4) ----------

5) ----------

PART E: Approvals

Request Approved By:

i. Head, SERU: ---------- Date: ----------

ii. Director, KEMRI: ---------- Date: ----------

KENYA MEDICAL RESEARCH INSTITUTE

4. SCIENTIFIC AND ETHICS REVIEW UNIT (SERU)

5. AUTHORITY TO EXPORT BIOMEDICAL RESEARCH MATERIALS*

This is to certify that _____

Principal Investigator/Co-Principal Investigator/Investigator in the research project titled:

_____

_____

_____

and referenced SERU/SSC No: _____being undertaken in collaboration with the

Kenya Medical Research Institute (KEMRI) has been granted permission to send out

_____

(Number and Description of the Samples)

to_____

(Name of Department and/or Institution)

in_____

(Country of Destination)

for the purpose of_____

_____

_____

(Description of the type(s) of investigations or analyses to be conducted on the samples)

This certificate is issued with the understanding that the investigator will not use the samples for purposes other than those stated above. The investigator will submit a copy of the results of the investigations/analyses undertaken on these samples to the Director, KEMRI; and will ensure that KEMRI's intellectual property rights arising from work on the stated samples will be protected and safeguarded, and the findings thereof are published with the approval of the Director, KEMRI.

Recommended by:

_____

Name and Signature of Centre Director **Date**

Authorized by:

_____

Name and Signature of Director, KEMRI
Date

***This certificate is valid for a period of 90 (Ninety) days with effect from the date of authorization. Please direct any queries to the Director, KEMRI, P.O. Box 54840-00200 Nairobi, Kenya; Phone:**

(254-20) – 2722541; Fax: (254-20) – 2720030; E-mail: director@kemri.org

ANNEX 2_SERU FORM FOR IMPORTATION OF SAMPLES

GUIDELINES FOR IMPORTATION AND STORAGE OF HUMAN BLOOD AND OTHER BIOLOGICAL SAMPLES FOR RESEARCH

I. PREAMBLE:

KEMRI (herein referred to as the "Institute") collaborates with numerous research scientists, research organizations, and academic institutions throughout the world. Many a times local scientists or collaborating scientists from other countries request for importation or storage of human blood and other biological samples for research purposes. However, no clear guidelines are currently in place in the Institute to regulate this process, and to fully safeguard the interests and rights of study subjects and the Kenyan public in general. The following guidelines are designed for the purpose of regulating importation and storage of human blood samples and other biological materials, and safeguarding the Kenyan public against experimentation without their consent or approval of the Institute.

II. GUIDELINES:

1. No human blood or other biological materials may be brought into Kenya by an individual or groups of individuals working in or with the Institute, without the permission and approval of the Director, KEMRI, on the advice of the SERU and the Office of Health, Safety and Environment; and any other relevant institutions.

2. Investigators anticipating to store (for an extended period beyond study duration) or to take human blood and other biological materials into the country for further research or analysis, have to state so in their research proposals. If multiple shipments of samples into the country is anticipated, a separate request and approval will be needed for each shipment. All requests for sample storage or importation will be made on Form SERU x/xx(x) of the SERU, when need arises.

3. In the case of studies involving human subjects outside the country, the study subjects **MUST** have consented to importation or storage of samples taken from them,

and this must be reflected in the consent seeking and study explanation documents of the research protocol. Study participants have the right to refuse specimen storage or importation.

4. In the event that an investigator needs to store or import specimens obtained from human subjects outside the country, and consent for this was never obtained, approval must be sought from SERU.

5. If extended storage of samples (beyond the duration of the current study) is anticipated, the Principal Investigator (PI) of the study must state so in the research proposal, and when completing the request form, he or she has to indicate the location of sample storage, duration of storage (e.g. indefinitely or for a specific period), and reasons for storage.

6. In the event that further studies (other than those stated in the research protocol) are proposed on the stored or imported samples, approval must be sought from the IRB/ERC of the home institution of the human subjects in the study.

7. For importation, the recipient centre/unit/project (i.e. where the human blood or other biological materials will be sent to) should be indicated in the importation form, and the Director, KEMRI will sign a declaration, accepting responsibility and control over usage of these samples.

9. The name(s) of the individual(s) responsible for the transportation/storage of the blood or other biological samples, and the tests to be performed on the samples in the country of destination should be indicated in the request form. A Kenyan investigator should be included in the team to undertake the proposed or planned investigations/analyses in the recipient country, as part of human resource development and technology transfer. If a Kenyan investigator is not involved, an explanation must be provided.

10. The individuals requesting approval to import or store human blood and/or other biological specimens **must** undertake to declare the results of their investigations/analysis to the Institute, and ensure that any publications arising from the studies will acknowledge the involvement and contributions of the Institute, and in the case of publications, the approval of the Director KEMRI and

Director of the institution affiliated to the individuals importing to publish the research findings.

KENYA MEDICAL RESEARCH INSTITUTE

SCIENTIFIC & ETHICS REVIEW UNIT (SERU)

REQUEST FOR IMPORTATION OR STORAGE OF HUMANBLOOD AND OTHER BIOLOGICAL MATERIALS FOR RESEARCH

PART A: Project Information

i. Project Title:

_____

_____

SERU/SSC No: _____

ii. KEMRI Centre/Unit/Project of Affiliation:

_____

iii. Principal Investigator(s):

NAME	INSTITUTION	TELEPHONE	EMAIL ADDRESS

iv. Other Investigators:

NAME	INSTITUTION	TELEPHONE	EMAIL ADDRESS

PART B: Specimen Details:

i. Is the request for specimen IMPORTATION or storage or both?

(Request for storage is necessary if the samples are to be stored beyond the duration of the present study)

ii. Description of specimen(s) to be imported/stored:

---

iii. Reason(s) for importation/storage of samples:

1. ----------
-

2. ----------
-

3. ----------
-

vi. Duration of specimen storage: ----------
---

vii. **For samples originating from human subjects, state whether or not written consent for specimens importation or storage**:

PART C: Declarations: (To be completed prior to requesting for importation)

i. Declaration by the PI/ Investigator requesting importation/storage of research specimens:

I certify that the information provided in this request form is true and correct to the best of my knowledge, and I hereby declare that the specimens referred to herein will be utilized for the stated purpose only

Name:---------- **Role in the Project**:----------

--

Signature:---------- **Date**:----------

--

ii. Declaration by Exporting Institution:

This is to certify that the specimens referred to herein being sent to ----------
----------(Principal Investigator-Centre/Unit/project) for further

analyses/experimentation will be in the custody of the (Name of the recipient Institution) ----------, and I hereby confirm that they will be utilized for the purpose stated in this request form, and_____ (Name of PI) will accept full responsibility and control over the usage of these samples.

I further confirm that the study participants in this project have consented in writing to the exportation/ storage of samples taken from them, for use in further research.

Name of the Exporting officer: _____

Designation: _____

Name of Department/Institution Head: _____

Signature: _____ **Date**: _____

.

PART D: Approvals of Importation of Biomedical samples

Request Approved By:

i. **Centre Director;_____Date_____**

Signature: _____

ii. **Head of Department, Office of Health, Safety and Environment:**

_____ Date: _____

Signature: _____

iii. **Head, SERU: _____Date:_____**

Signature: _____

iv. **Director,KEMRI:_____Date:_____**

Signature: _____

v. KENYA MEDICAL RESEARCH INSTITUTE

6. SCIENTIFIC &ETHICS REVIEW UNIT (SERU)

7. AUTHORITY TO IMPORT BIOMEDICAL RESEARCH MATERIALS*

This is to certify that _____

Principal Investigator/Co-Principal Investigator/Investigator in the research project titled:

_____

_____

_____

being undertaken in collaboration with the Kenya Medical Research Institute (KEMRI) has been granted permission to ship in

_____

(Number and Description of the Samples)

to_____

(Name of Department and/or Institution)

in_____

(Country of origin)

for the purpose of_____

_____

_____

(Description of the type(s) of investigations or analysis to be conducted on the samples)

This certificate is issued with the understanding that the investigator will not use the samples for purposes other than those stated above. The investigator will submit a copy of the results of the investigations/analyses undertaken on these samples to the Director, KEMRI; and will ensure that KEMRI's intellectual property rights arising from work on the stated samples will be protected and safeguarded, and the findings thereof are published with the approval of the Director, KEMRI.

Recommended by:

_____**Date** _____

Name and Signature of Head, SERU

Authorized by:

_____**Date**_____

Name and Signature of Director, KEMRI

***This certificate is valid for a period of 90 (Ninety) days with effect from the date of authorization. Please direct any queries to the Director, KEMRI, P.O. Box 54840-00200 Nairobi, Kenya; Phone:**

(254-20) – 2722541; Fax: (254-20) – 2720030; E-mail: director@kemri.org

ANNEX 3: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal Investigator	Submitting applications for Import and Export of biological samples	
Shipment Compliance Officer	Receives, pre-reviews and records all import and Export requests for biological Samples applications submitted to SERU	
Head SERU	Head SERU Signs the letter