KENYA MEDICAL RESEARCH INSTITUTE

SCIENTIFIC AND ETHICS REVIEW UNIT (SERU)

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

# 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.

1. **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.

1. 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.

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## 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:**

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

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

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

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

1. **Duration of specimen storage: -------------------------------------------------------------------**
2. **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:**

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

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## 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)**

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

**Sign**------------------------------

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

**Sign**------------------------------

1. 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

# SCIENTIFIC AND ETHICS REVIEW UNIT (SERU)

# 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**:

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 **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**