In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR SECONDARY USE OF BIOLOGICAL SAMPLES

Document Control Schedule

Name of department:	**SERU**
Document Type:	**Management Procedure**
Document Ref:	**KEMRI/SERU/SOP/PI/SUBS**
Process owner:	**Head Compliance SERU**
Signature:	
Approved By:	**Head SERU**
Signature:	
Effective Date:	**October 18, 2017**

TABLE OF CONTENTS

1. PURPOSE

The purpose of this SOP is to describe the requirements for IRB approval and informed consent for previously collected biological samples used for secondary research.

2. SCOPE

This SOP describes the steps to be taken by P.Is who wish to submit a request for approval to use biological samples for research purposes other than what they were initially collected for.

3. INTRODUCTION

SERU approval is required for secondary research uses of previously collected biological samples, to ensure that such use is in keeping with human participants' protection requirements and that it does not compromise the participants' rights in any way.

4. TERMS & DEFINITIONS

4.1 Sample/specimen: - Human biological material, including solid material (e.g., tissue, organs), body fluid (e.g., blood, urine, saliva, semen, cerebrospinal fluid), and cells.

4.2 Anonymous samples: - samples for which identifiers/personally identifiable information were not collected or from which identifiers were removed irretrievably such that they cannot be linked directly or indirectly *by anyone* to their source(s).

4.3 Coded samples: - samples for which direct personal identifiable information has been removed and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s); but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code.

4.4 De-identified samples: All direct personal identifiers are *permanently* removed (e.g., from data or specimens) and no code or key exists to link the samples or materials to their original source(s), and the remaining information cannot reasonably be used *by anyone* to identify the source(s).

4.5 Secondary use of biological samples: Study of existing samples that have been previously collected for a purpose (including non-research purposes) other than the currently proposed activity.

4.6 Sample repository/bank: Collection of samples obtained and stored for future research uses and/or distribution, including a collection not originally or primarily obtained for research purposes

5. OBJECTIVES

To ensure secondary use of biological samples applications are received effectively and efficiently.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Record of applications received

8. KEY PERFORMANCE INDICATORS

8.1 Number of applications received

9. RESPONSIBILITY AND AUTHORITY

9.1 SERU Committee: - reviews all new applications requesting use of archived samples at its next available meeting provided the applications are received by the SERU Secretariat on or before the deadline for submission.

10. DETAILS OF PROCEDURE

10.1 The P.I submits a request for secondary/new uses of biological samples obtained for *primary research purposes* either as an amendment or a new protocol describing the proposed secondary use, depending on the previous approval and the new research objective(s).

10.2 The P.I submits a request for secondary use of biological samples detailing the following:

10.2.1 The specific purpose for which the samples are to be used

10.2.2 A disclosure of the name of the PI for each of the studies from which the samples will be obtained.

10.2.3 A disclosure of the study or studies (give titles and any SERU study identification numbers) from which the samples were derived

10.2.4 Circumstances under which the samples were collected

10.2.5 Physical location/equipment and security provisions for sample storage

10.2.6 Evidence that scientific review of the proposed study has been done to ascertain the merit in conducting the study

10.2.7 The number and types of samples to be obtained from each study for secondary use

10.2.8 The state of the samples e.g. anonymous, de-identified, coded, identifiable, etc

10.2.9 If the samples are linked to individually identifiable protected health information

10.2.10 Evidence of an assessment of the integrity of the archived samples to be used to ensure that the samples in question are suitable for use in the proposed study and that they will yield meaningful results.

10.2.11 An analysis on the limitations (of the new study) presented by the criteria for collecting and storing the samples and how these limitations will be addressed.

10.2.12 A disclosure of whether the PI of the new study can link the specific samples to the individuals or the community from which the samples were obtained either directly or indirectly through an existing code, coding system or by a combination of variables that can result in identification of an individual or community or whether anonymized samples (i.e. stripped of all identifiers) will be used.

10.2.13 The arrangements for obtaining participant consent and/or privacy protections where it is possible to identify the samples

10.2.14 The identification of the samples must be limited to the extent necessary to achieve the study objectives and a justification should be provided.

10.2.15 A detailed description of the agreements between the investigators on transfer and storage of the biological samples, ownership of data, findings or intellectual property rights (IPR)/patents.

10.2.16 A copy of the previously approved consent document used for the initial collection of the biological samples indicating that the participant was consented for collection, future use and/or long-term storage of their samples.

10.2.17 Process for destruction or de-identification of identifiable or coded samples at the end of the storage period

10.3 Informed consent considerations:

10.3.1 Research using previously collected samples must be consistent with the scope and terms described in the original informed consent process/document, as applicable.

10.3.2 If consent was not obtained (e.g. samples obtained for non-research purposes) or the original consent does not adequately include the proposed secondary use, specific informed consent for the new research may be obtained where possible. If not possible to obtain informed consent, the P.I may request SERU to waive the consent requirement for use of the samples in a de-identified or anonymized manner and clearly demonstrate why the research is justifiable.

10.3.3 Adequate informed consent is required for secondary use of identifiable biological samples. If not possible to obtain informed consent, the P.I may request SERU to waive the consent requirement for use of the samples in a de-identified or anonymized manner and clearly demonstrate why the research is justifiable.

10.3.4 For samples collected and archived without consenting of the participants for future potential use and long-term storage, the P.I should justify the scientific merit in using the archived samples. The P.I should seek SERU's approval for the use of the samples provided that the samples will be anonymized or coded and the research is being conducted in line with the objectives of the initial study for which the samples were collected or a justified public health concern.

10.3.5 For secondary use of biological samples that is likely to produce information relevant to the health or wellbeing of the person who gave the sample, the P.I should ensure that appropriate follow-up is done where it is possible to re-contact the study participant.

10.3.6 *NB: Secondary use of isolates in a de-identified or anonymized manner does not require informed consent*

10.4 Data sharing considerations

10.4.1 The P.I is required to seek SERU approval prior to sharing samples with collaborators for secondary research purposes

10.4.2 If the P.I plans to distribute samples for secondary research uses beyond a single transfer described in a specific SERU-approved protocol, they must clearly justify to SERU the reason for this; In some instances, the P.I may be required to seek SERU approval for a sample repository

10.4.3 The P.I should submit material transfer agreements (MTAs), and any other relevant agreements, to be used for the sharing of research samples with non-institutional collaborators

10.5 The P.I. receives SERU's review outcome, in writing, within six (6) working days of the meeting at which the decision was reached.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of secondary use of biological samples	Principal Investigator's application missing some documents required before acceptance	Principal Investigator failing to submit all the required documents before acceptance of application	Training all Principal Investigators about the documents required for the submission of an application requiring the use of biological samples

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunity
Submission of secondary use of biological samples	Training all Principal Investigators about the documents required for the submission of an application requiring the use of biological samples	1. Attending trainings for KEMRI and non KEMRI principal investigators about the requirements for successful submission of applications.

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 Research involving data and/or biological specimens – Ohio State University (http://orrp.osu.edu/files/2012/02/Research-Involving-Data-andor-Specimens.pdf)

13. ANNEXES

13.1 Annex 1 – SERU Materials Transfer Agreement Template
13.2 Annex II – Process flow chart

ANNEX 1: MTA TEMPLATE

MATERIAL TRANSFER AGREEMENT

[Instructions: Please replace the italicized areas with the appropriate information and then delete this instruction before submitting to Recipient and the Director, KEMRI for authorisation.]

This Material Transfer Agreement (hereafter "MTA") is effective on the date of the latter of the two authorized signatures of parties. The parties of this agreement are:

PROVIDER: Kenya Medical Research Institute
P.O. Box 54840 00200 Off Mbagathi Road,
Nairobi, Kenya.
(Provider's Scientist)
(Laboratory)
(Provider's Laboratory Head)

RECIPIENT: Institution receiving the Original MATERIAL: ***(Enter name and address here)***
Recipient's Scientist: ***(Enter name and address here)***
Laboratory: ***(Enter name of lab)***

Under this MTA, the provider agrees to transfer material to the recipient, collectively referred to as the "Parties" and individually referred to as a "Party", under the following terms and conditions:

1. The Material. The material being transferred to Recipient is defined as: *(specify material here and give a description).* (together with all analogs, formulations, mixtures or compositions thereof, the "Material").
2. The Research Program. The Material is provided to Recipient for the following use(s) only: *(Specify what the material will be used for)* and described in detail in the Protocol that is attached to and made part of this Agreement (the "Research Program").

3. Use of the Material. The Material is not for use in humans, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider. The Material is not to be given or made available to any third party or person, except Recipient's employees, consultants, contract research organizations or collaborators that are bound by terms and conditions similar to the terms and conditions that are contained herein, and shall not be used for any purpose other than for the Research Program. All requests for the Material from a third party other than Recipient's employees, consultants, contract research organizations or

collaborators will be referred to the Provider. Recipient agrees to use the Material and conduct the Research Program in a safe manner and in compliance with all applicable Federal, State, and local laws and regulations, including relevant National Institutes of Health guidelines.

4. Ownership. The ownership of the Material shall remain with Provider, including intellectual property rights of Provider embodied in the Material. Except as specifically provided in this Agreement, no express or implied licenses or other rights are provided to Recipient under any intellectual property rights of the Provider in respect of said Material.

5. Reports. Recipient shall keep Provider reasonably informed about the progress of the Research Program and shall provide reports to Provider on the results of the Research Program as outlined in the research plan. Provider may use and allow others to use the research results for any and all lawful purposes.

6. Inventions. Recipient will promptly and fully disclose in writing to Provider any and all developments, inventions and know-how (whether or not protectable under state, federal, or foreign intellectual property laws) related to the Material or its use, or developed using the Material, which are conceived and/or reduced to practice by Recipient, alone or jointly with others, in the performance of the Research Program (the "Inventions"). Inventions will be owned in accordance with inventorship as determined under KEMRI Intellectual property policy. Recipient grants to Provider (a) a non-exclusive, royalty-free license to Recipient's interest in all Inventions to use the Inventions for research purposes and to make, have made, use, have used, sell and have sold, any products that are covered by or incorporate any such Inventions and (b) a first right to negotiate an exclusive, royalty-bearing license to Recipient's interest in all Inventions (the "Right of First Negotiation"). Such non-exclusive license and license obtained under the Right of First Negotiation shall be irrevocable and shall include the right to grant sublicenses. For each Invention, Provider's Right of First Negotiation may be exercised in writing (the "Notice") within ninety (90) days of disclosure of that Invention to Provider by Recipient. The royalty payable to Recipient and other terms of the license pursuant to the Right of First Negotiation will be negotiated by the Parties in good faith for a period of up to ninety (90) days after the date of the Notice (the "Negotiation Period"). During the Negotiation Period, Recipient shall not engage in any negotiations or discussions with any third party regarding a license to the Invention. This Agreement does not restrict Provider's right to distribute the Material to other commercial or noncommercial entities.

7. Patent Filings. Any patent applications necessary to protect the interests of the Parties in any Inventions made solely by Recipient will be prepared, filed and prosecuted by Recipient, solely in Recipient's name, with the expenses paid by Recipient. Any patent applications necessary to protect the interests of the Parties in any Inventions made jointly by Recipient and Provider will be prepared, filed and prosecuted by Provider, jointly in its and Recipient's names, with expenses paid by Provider. If Provider exercises its Right of First Negotiation and executes

an exclusive royalty-bearing commercialization license to an Invention under Section 6 above, Provider will reimburse Recipient for its reasonable patent expenses related to such Invention.

8. Term/Expiration. The term of this Agreement shall be for a period of one (1) year from the Effective Date (the "Term"). At the end of the Term, any remaining Material shall be returned to Provider or destroyed, as instructed by Provider. The Term of the Agreement may be extended for an additional specified period upon the written agreement of authorized representatives of the Parties. Sections 5, 6, 7, 8 (last sentence only), 9, 10, 11, 12, 13 and 16 through 18 shall survive the expiration or earlier termination of this Agreement.

9. Confidentiality. "Confidential Information" means any and all proprietary or confidential scientific, technical, financial or business information in whatever form (written, oral or visual) that is furnished or made available to a party (the "Receiving Party") by or on behalf of the other party (the "Disclosing Party"). During the Term and for a period of five (5) years from expiration of the Term, Receiving Party agrees not to disclose any of Disclosing Party's Confidential Information nor use such information other than in connection with the Research Program. This obligation of confidentiality shall not extend to Disclosing Party's Confidential Information which (a) at the time of disclosure is in the public domain; (b) after disclosure becomes part of the public domain, except by breach of this Agreement by Receiving Party; (c) was in the possession of Receiving Party at the time of disclosure and was not acquired, directly or indirectly, from Disclosing Party under an obligation of confidentiality, as established by competent written evidence; (d) Receiving Party received or may receive from a third party who is not, directly or indirectly, under an obligation of confidentiality to Disclosing Party with respect to such information; or (e) is approved for public release by written authorization of Disclosing Party. Receiving Party may disclose Disclosing Party's Confidential Information if required by court order or otherwise by operation of law, provided that Receiving Party provides prior written notice of such disclosure to Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the extent of such disclosure.

10. Publication. The Parties contemplate that the results of research performed with the Material may be published. Publication includes dissemination in a presentation or in any other way, provided the information has not previously been released to the public. Acknowledgement shall be made for the contributions of each Party, including the origin of the Material.

Notwithstanding the above, Recipient shall provide a copy of any proposed publication resulting from the Research Program to Provider at least thirty (30) days in advance of the submission of such publication to a journal or editor. Provider shall have thirty (30) days after receipt of said copy (the "Review Period") to review the submitted documents. Provider may require that Recipient delete from its documents any reference to Provider's Confidential Information. If, during the Review Period, Provider notifies Recipient that it desires to file a patent application on any Invention disclosed in the documents, Recipient will defer publication/presentation for up to sixty (60) additional days from the date of such notification to permit Provider to prepare and

file a patent application. Failure of Provider to respond within the Review Period shall constitute *de facto* agreement of Provider that no revisions or delay in publication is necessary.

11. NO WARRANTY. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

12. Indemnification. Recipient agrees to indemnity, defend and hold Provider harmless from any third party claim, (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "Claims"), to the extent based upon, arising out of, or otherwise relating to Recipient's use of Material. The previous sentence will not apply to any Claim that results from the negligence or willful misconduct of Provider.

13. Except to the extent prohibited by law, RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. PROVIDER will not be liable to RECIPIENT for any loss, claim or demand made by RECIPIENT, or made against RECIPIENT by any other party, due to or arising from the use of the MATERIAL by RECIPIENT, except to the extent caused by the gross negligence or wilful misconduct of PROVIDER.

14. Modifications/Severability. This Agreement may only be modified by written amendment signed by an authorized representative of each Party. If any provision of the Agreement is found to be unenforceable, such provision will be limited or deleted to the minimum extent necessary so that the remaining terms remain in full force and effect.

15. Assignment. No obligations or rights under this Agreement may be assigned or delegated by Recipient without the prior written consent of Provider (which consent shall not be unreasonably withheld). This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective heirs, legal and personal representatives, successors and permitted assigns.

16. Remedies. The provisions of this Agreement are necessary for the protection of the business and goodwill of the Provider and are considered by the Parties to be reasonable for such purpose. Recipient agrees that any breach of this Agreement may cause Provider substantial and irreparable harm and, therefore, in the event of any such breach, in addition to other remedies that may be available to Provider, Provider shall have the right to seek specific performance and other injunctive and equitable relief without the necessity of posting a bond.

17. RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.

19. The MATERIAL is provided at no cost, or with an optional fee to reimburse the PROVIDER for its preparation and shipping costs.

Fee for MATERIAL: _____

20. This MTA constitutes the entire agreement between the PROVIDER and RECIPIENT concerning the MATERIALS and supersedes any prior understanding or written or oral agreement.

1.1.1.1.1.1

1.1.1.1.1.2 **[Each party shall sign three (3) identical copies of this MTA, one of which shall be kept by PROVIDER, one by RECIPIENT and another by KEMRI/SERU]**

(Signatures begin on the following page.)
ACKNOWLEDGED AND AGREED TO BY:

For Provider:

_____
Signature

_____
Name and Title (please print)

_____
Date

For Recipient:

_____
Signature

_____
Name and Title (please print)

_____
Date

PROTOCOL

Material Transfer Agreement with *name of the recipient* (Recipient)

1) The following samples will be collected and transferred to the *(Insert name and address of the laboratory the material is going to)*:

   1.1.1.2
   Provide description of the samples as per the protocol;.

2) The following tests and frequency will be performed at the *xxxx* Laboratory:

Sample	Type	Assessments

ANNEX 2: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	Submitting secondary use of biological samples applications	
Centre Compliance Officer	Receives, pre-reviews and records all secondary use of biological samples applications submitted to SERU