KEMRI Scientific and Ethics Review Unit
Standard Operating Procedures (SERU SOPs)

Version 1.0

Dated 27-SEP-2016
DEFINITION OF TERMS

- “Advice” means an opinion recommended or offered with the intention of providing ethical or technical assistance to those involved in research.
- “Applicant” means a qualified researcher requesting or seeking a decision from the SERU through a formal application.
- “Application” means a document containing a request for SERU consideration.
- “Assent” means an affirmative agreement of a child (aged 12-17 years) or an individual with impaired consent capacity to participate in research. Mere failure to object i.e. absence of affirmative agreement should not be construed as assent.
- “Baraza” means a deliberation meeting convened by a community elder or a government representative to discuss specific issues(s) affecting the community or that is likely to affect the community.
- “Benefit” means a valued or desired outcome.
- “Child” means an individual who has not attained the legal age to provide consent to treatments or procedures involved in a particular research.
- “Community” means a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.
- “Community Advisory Board (CAB)” means a group of volunteers that serve as a link between a community and researchers and may review and monitor research studies and help teach the community about the studies.
- “Conflict of Interest” means a situation in which a member (or members) of the Scientific and Ethics Review Unit (SERU) decisions are influenced by the member’s personal interests in a particular research proposal.
- “Deception” means an act designed to mislead a study participant by manipulation or perversion of facts to induce the individual to react in a manner that serves the PI’s interests.
- “Decision” means a position, judgment or opinion reached by the SERU to an application following review.
- “Scientific and Ethics Review (SERU) Committee” means a panel of individuals who review research proposals to ensure that the scientific and ethical principles are incorporated into the study design, that the proposed research activities include no unnecessary risks, that potential risks to study participants are minimized, and that overall potential benefit to the individual, or to society, is reasonable in relation to the risks.
- The SERU also considers the importance and significance of the scientific knowledge potentially gained against risks to study participants. This Committee is designated by KEMRI to approve the initiation of and conduct periodic review of all approved research.

- “Expected Adverse Event” means any adverse experiences that have been identified in nature, severity, or frequency in the current clinical investigational brochure, study protocol and current consent forms.
- “Gene therapy” means the treatment of disease by replacing damaged or defective genes with normal ones.
“Genetic Material” means any tissue sample that can serve as a source of DNA or RNA; including blood, saliva and any other tissues or body fluids containing nucleated cells from which DNA can be isolated.

“Investigator” means a qualified scientist who devotes himself/herself to research and undertakes scientific and ethical responsibility of a research project at a specific site or group of sites.

“Investigational device” means a medical device which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

“Informed Consent” means the permission given by an individual who understands the purpose and nature of a study, what participation in the study requires of the individual, the nature of the risks and what benefits are intended to result from participation in the study.

“Legally Authorized Representative” means an individual, judicial or other person authorized to consent on behalf of a research study participant to his or her participation in the procedure(s) involved in a particular research.

“Medical device” means any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized.

“Minimal risk” means the probability and magnitude of discomfort or harm anticipated in a given research are no greater than those typically encountered in daily life or during the performance of routine physical or psychological examinations or tests.

“NON-SSC/NON KEMRI Research Proposal” means a proposed research from investigators who are not affiliated with KEMRI or KEMRI’s research partners but will be conducted in Kenya in facilities that are not under the jurisdiction of the Kenyatta National Hospital-University of Nairobi Research Ethics Committee or the Moi University Teaching and Referral Hospital Institutional Research and Ethics Committee. NON-SSC/NON KEMRI proposals are typically evaluated for their scientific soundness by a duly constituted Scientific Review Board of the home institution of the principal investigator.

“Observer” means an individual who attends and reports on the proceedings of a SERU committee meeting, within the provisions of the confidentiality agreement, but does not vote or otherwise participate.

“Permission” means an agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in SOP 7.

“Principal Investigator” means a person having the background and training in scientific and administrative oversight necessary to conduct and manage a sponsored project. All SERU applications must be submitted by the principal investigator.

The principal investigator is ordinarily the first named investigator who is held responsible for the conduct of the study and for maintaining the approval status of his/her study. He/she receives all correspondence related to the study.

“Protocol” means a document that provides the background, rationale, and objective(s) of a research study and describes its design, methodology, and organization, including ethical and statistical considerations and data analysis plan.

“Protocol amendment” means a written statement that is added to, or revises, or improves an ongoing research study that has obtained approval from SERU.

“Provisional approval” means a temporary authorization granted by a SERU Committee Chairperson that entitles a PI prepare for the implementation of a new study or an
amendment to an approved study with the possibility of being ratified or change by a convened SERU committee.

- **“Requirements”** means an essential conditions that the SERU considers or views as obligatory in pursuing the research.
- **“Research”** means a systematic investigation including research development, testing and evaluation, designed to improve on or contribute to generalizable knowledge.
- **“Research participant”** means a living individual who participates in a research project, either as the direct recipient of an intervention, as a control, or through observation or interaction. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research being carried out but who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.
- **“Research Site”** means a single institute responsible for hosting research at a particular area in Kenya.
- **“Research Study”** means Research into questions posed by scientific theories and hypotheses and conducted under stipulated scientific and ethical rules.
- **“Sponsor”** means an individual or organization that takes on ultimate responsibility for the initiation and management (or arranging the initiation and management) of, and the financing (or arranging the financing) for a particular study.
- **“Traditional Medicine”** means any health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercise, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain wellbeing.
- **“Unexpected Adverse Event”** means any adverse experience which is not consistent with the current investigator brochure or an experience that has not been previously observed including events that are more serious than expected or occur more frequently than expected.
1.1 Offices

1.1.1 The Head of the SERU

The Head of SERU should have an in-depth knowledge of ethical and scientific issues in the conduct of research, the law and the KEMRI Research Policy.

The responsibilities of the Head of SERU shall include (but not be limited to) the following:

a. To represent the SERU in discussions with the KEMRI administration.
b. To assist the Director KEMRI in the recruitment of new SERU committee members.
c. To facilitate the induction of new SERU committee members.
d. To present periodic reports to the KEMRI Board during each fiscal year, highlighting the following items:
   - The SERU committee(s) membership or change in membership.
   - The number of meetings held.
   - The number of applications received and reviewed.
   - The number of applications approved or disapproved.
   - Monitoring and evaluation of research activities done including protocol deviation or protocol violations and their resolutions, study status evaluations and the recommendations, report of any site visit(s) made, any new information received that is pertinent to human study participant involvement and how it has been handled.

e. To conduct an evaluation of the performance and the services provided by the SERU secretariat and take appropriate action.

1.1.2 The Head of Department (HOD) Quality Assurance, Monitoring and Evaluation (M AND E)

The activities outlined in this Section shall be overseen/ coordinated by the Head of Department, Quality Assurance, Monitoring and Evaluation. This department shall work hand-in-hand with the Departments of Training and Research Regulation. The Head of the Department of Quality Assurance, Monitoring and Evaluation shall report to the Head, SERU. The responsibilities of the Head, Quality Assurance, Monitoring and Evaluation shall include (but not be limited to) the following:

a. Monitoring and Evaluation of Secretariat Activities

   Monitoring and quality improvement is an important responsibility of the Scientific and Ethics Review Unit (SERU). The Quality Assurance and Monitoring Department (henceforth referred to as “the department”) shall continuously monitor the following activities of the SERU Secretariat (but not be limited to):
   - Secretariat activities,
   - Customer satisfaction with receipt of documents and applications (that is, the Principal Investigators {PI} and SERU committee members’ satisfaction),
• Time when packets are distributed (in relation to the next scheduled meeting) to the committee members for review,
• Dispatch of letters to the PIs after meetings,
• Time to approval from initial submission,
• Time from initial receipt at SERU to first official communication to the PI,
• Overall customer satisfaction with the research regulation process,
• Timelines for expedited reviews,

The information produced in these reports shall be used to find ways of increasing efficiency, improve customer satisfaction and to improve the quality of the Secretariat’s work.

b. Monitoring of the SERU Committee(s), their Members and Functions
It is also of vital importance to monitor the performance of individual members and the various committees during the discharge of their duties. The department shall monitor committee and member activities including (but not limited to) the following:
• Member attendance records,
• Provision for attendance with/without reviews,
• Absent with/without comments,
• Timeliness and overall/actual submission of typed comments,
• Quality of review,
• Committee members’ satisfaction with the secretariat processes,
• Monitoring committee and individual member adherence to SERU SOPs,
• Checklists/ comments.

This information shall be provided to KEMRI’s top Management, the Secretariat and SERU committee members biannually.

The reports produced may be used during the performance evaluation of the committees and their members, and during the renewal of committee member contracts.

c. Monitoring of research implementation (Refer to Sop 18: Monitoring of approved studies)
The various research studies should be monitored to ensure adherence to implementing the approved Protocol, and compliance with human subject protection expectations. The following may inform the need to monitor such as (but not limited to):
• Frequent safety adverse event (SAE) reports,
• Whistle blower information,
• Major deviations and/or protocol violations,
• High risk studies,
• Studies involving vulnerable populations,
• Severe unexpected/unanticipated SAEs,
• Reports of misconduct and complaints,
• Concerns arising from review of study documents.

d. Central data base for SAE/AEs reporting and monitoring
• In order to monitor SAE reporting, the department shall create and maintain a central database. The purpose of this database is to ensure that studies with many reported SAEs or with SAEs that lack critical information are identified. The extracted information from the tracking process will provide important information to be used for decision making in regards to continued approval and implementation of the study, and shall also help in identifying the needs for a monitoring visit to the study sites, or additional training.

• The department shall also monitor adherence to timelines for submission of the hard and soft copies of the SAEs.

1.1.3 The Training Department

The Head of the Training Department must have an in depth understanding of ethical issues in the conduct of human research in addition to experience in research ethics and training.

The responsibilities of the Head, Training Department shall include (but not be limited to) the following:

a. To ensure regular certification of investigators, SERU secretariat staff and SERU committee members. Certification shall include but not be limited to CITI and other training areas such as:
   • Training on emerging issues on research ethics,
   • Training on SERU SOPs and other relevant documents,
   • Training on review of proposals,
   • Training on communication skills,
   • Keeping updated training logs.

b. To create and maintain an ethics resource centre.

c. To coordinate and facilitate routine training of staff by:
   • Conducting regular face to face ethics trainings,
   • Identifying training opportunities in research ethics,
   • Initiating and maintaining regular journal clubs and seminars and workshops for SERU secretariat and members,
   • Developing innovative ways of training on ethics such as facilitating webinars and video presentations.
   • Research regulation administration training.

d. To develop a research regulation training curriculum by:
   • Conducting need assessment surveys to identify training needs of researchers and reviewers,
   • Based on information obtained from the QA and Monitoring Department during monitoring visits, to develop a training curriculum for researchers.

e. To respond to independent requests for training from researchers, Centres and other ethics committees etc.

f. To coordinate efforts for capacity building by:
   • Applying for grants for research, training and conferences/workshops,
   • Team building activities and Retreats.
1.1.4 Department of Research Regulation

The Head of Department, Research Regulation shall report to the Head, SERU.

The activities of the department shall include (but not be limited to) the following;

a. Oversee the secretariat at the initial process of protocol review at the SERU, and the basic day-to-day running of the secretariat;
   - The head of department shall be in charge of who will receive different kinds of applications e.g. new applications, amendments, resubmissions, continuing review reports (CRRs), shipments, safety reports, deviations/violations, Investigators Brochure, notifications among others,
   - Overseeing agenda preparation, distribution and delivery of packets,
   - Overseeing expedited review applications, distribution and delivery,
   - Tracking reviewers’ comments,
   - Letter writing including drafting and allocation of letter templates, quality assurance/quality control (QA/QC) of letters before signing, submission of letters to Head, SERU for signing, overseeing dispatch of letters at the right time to various PIs,
   - Overseeing allocation to reviewers the resubmitted applications as well as ensuring comments are submitted in good time,
   - Overseeing applications for shipment of biological samples and specimens,
   - Preparing the job description of various officers of the SERU Secretariat.

b. Maintain detailed knowledge of all the assigned protocols and ensure that all the study personnel adhere to all protocol requirements to ensure validity of research applications.

c. Responsible for the Triaging-Research Analyst process by:
   - Deciding whether an application can be reviewed by a convened SERU committee, as expedited or as quick turn around,
   - Assist in ensuring registration, accreditation and renewal of the SERU committees with the National Commission for Science, Technology and Innovation (NACOSTI) and the Office for Human Research Protections (OHRP). This shall be done through proper documentation of the SERU committees’ membership and relevant certifications.

d. Oversee the overall communication between the Secretariat and the PIs.

e. Communicate with other local and regional IRBs for example, in the requests for reliance agreements.

f. Planning the SERU Secretariat meetings for yearly, monthly and/or daily activities of the Secretariat.

g. Initiate amendments of standard operating procedures (SOPs) proposed and assist in the development of SOPs.

h. Implement a process to receive and act on complaints and allegations regarding research regulation for example, setting up suggestion boxes for feedback. This shall be done in collaboration with HOD QA and Monitoring.

i. Maintain the credentials of the SERU committee members and secretariat staff for instance curriculum vitae (CVs), trainings attended, ethics certifications etc. This shall be done in collaboration with the HOD Training.
1.1.5 The SERU Committee Chairperson(s)

The SERU Chairperson(s) must have an in-depth understanding of ethical issues in the conduct of human research, the law, NACOSTI and KEMRI research guidelines.

The responsibilities of the SERU Chairperson(s) shall be (but not limited to) the following:

a. To provide leadership in establishing and implementing guidelines and standard operating procedures for the SERU.

b. To assess conflict of interest reported by other SERU members.

c. To direct proceedings and discussions of the full SERU committee meetings.

d. To serve as a reviewer for research proposals under expedited review and/or designate at least three SERU committee members to conduct expedited review depending on their expertise.

e. To represent the SERU in defending or discussing SERU decisions with investigators.

f. To confirm and sign the minutes for the appropriate SERU committee meeting.

g. To represent the SERU committees in discussions between KEMRI and other institutions.

h. To write specific correspondence to an investigator or institution as agreed upon at a convened SERU meeting.

i. To carry out other duties common to all the SERU committee members.

1.1.6 The SERU Committee Secretaries

The SERU Committee Secretary shall be a Senior or Principal Research Analyst based at the SERU Secretariat.

The SERU Committee Secretary shall also carry out duties of a SERU committee member.

In addition, other responsibilities of the SERU Secretary shall include (but not be limited to) the following:

a. To coordinate routine functions of the SERU and work closely with the appropriate SERU Chairperson to provide for the efficient management of the SERU operations.

b. To represent the SERU in discussions with KEMRI and non-KEMRI affiliated investigators.

c. To call for and coordinate SERU meetings.

d. To coordinate and conduct educational activities designed to improve staff, and student knowledge of sound ethical research practices.

e. Any other duties as may be assigned by the SERU Head.

1.1.7 The SERU Committee Members

The SERU committee members shall be of diverse cultural backgrounds representative of the population in Kenya and the committee shall be gender balanced i.e. no more than sixty percent (60%) of either female or male.

The responsibilities of the SERU committee members shall include (but not be limited to) the following:

a. To develop an understanding of ethical principles of research involving human participants set forth in the KEMRI’s SERU SOPs, national and international guidelines and in the Office of Human Research Protections (OHRP) guidance.

b. To evaluate all proposed and continuing submitted to the committee.

c. To ensure that all approved studies comply with the terms and conditions of approval for the duration of the research.
d. To review the SERU committee documents and materials assigned to the member prior to the
SERU meeting and submit a written and typed report a day before each scheduled meeting.
e. To attend scheduled monthly meetings prepared to discuss proposals and items on the agenda
within the member’s area of expertise.
f. To identify and facilitate the resolution of any issues for a given proposal when appointed as
a designated reviewer.
g. To participate in expedited reviews when called upon by the SERU committee
Chairperson(s) and provide written and typed review comments.
h. To participate in and conduct educational activities in research ethics.
i. To participate in monitoring or audit functions of the SERU.

1.1.8 The SERU Secretariat

The SERU Secretariat Office (referred to hereafter as “the SERU Office”) staff shall be
composed of: The head of SERU, Chief, Principal, Senior, Research and Assistant Research
Analysts, an Administrator and support staff (including but not limited to a driver, an auxiliary,
security officer etc.)
The SERU office shall be located within the KEMRI Headquarters campus.
All staff of the SERU Secretariat shall be employees of KEMRI.

The activities of the SERU Secretariat shall include (but not be limited to) the following:

a. To provide support to the SERU committee Chairpersons and Secretaries in the review
process.
b. To serve as an interface for Centre Scientific Committee (CSC) Investigators, regulatory
authorities and any other stakeholders on matters of health research ethics.
c. To ensure that submitted research proposals or applications are reviewed.
d. To oversee the accurate and timely processing, tracking and filing of all applications.
e. To effectively communicate with investigators, SERU committee members, and other
interested groups in a timely manner.
f. To ensure that quorum is present and maintained during convened SERU committee
meetings.
g. To ensure that continuing review of research is conducted appropriately and in a timely
manner.
h. To maintain accurate records of the SERU committee actions.
i. To record minutes of the SERU committee meetings.
j. To document communication with investigators and others involved in the conduct of
research.
k. To maintain an accurate and comprehensive database of reviewed and approved research.
l. To maintain an accurate archiving system that allows for access to open and closed studies.
m. To update the SERU on any new information or regulation and changes affecting the SERU
function or protection of research participants.

Membership

a. The composition of the SERU shall be in compliance with the requirement noted in the
National Commission for Science and Technology and Innovation (NACOSTI) guidelines
and in the Assurance of Compliance filed with the Office of Human Research Protections (OHRP) of the US Department of Health and Human Services (DHHS).
b. The SERU Committee members shall be appointed by the Director of KEMRI, (referred to hereafter as Director, KEMRI).

c. Each SERU committee shall be composed of at least eight (8) members and a maximum of twenty (20) members with varying expertise and possessing the professional competence necessary to promote comprehensive ethical review of research initiatives at KEMRI.

d. The core membership shall include at a minimum:
   i. At least two (2) Clinicians;
   ii. At least two (2) Non-clinician Scientists (Biomedical Science);
   iii. At least one (1) Legal expert;
   iv. At least one (1) Theologian, Sociologist or Ethicist;
   v. At least one (1) Biostatistician or Epidemiologist;
   vi. At least one (1) Community Representative;
   vii. Such other members as may be deemed necessary.

e. The SERU committee members may be appointed in more than one of the above categories, but for each category, an alternate member may be appointed. The alternate member may replace a regular member who is unable to attend a convened SERU meeting and shall have qualifications comparable to that of the applicable regular member.

f. The SERU committee shall have the authority to co-opt a new member, with competence in a specialized field, onto the committee. The co-opted member shall assist in the review of complex issues which require expertise beyond or in addition to that available in the SERU but shall not participate in the final decision-making process on a particular research proposal or application.

Terms of Membership
a. Members should be willing to make public their full names, profession, and institutional affiliation.

b. Members shall be expected to declare any conflicts of interest which may arise or exist during their tenure on the SERU committee. Such conflict will be declared in writing before each meeting and documented in the minutes. Members will recuse themselves from any discussion of a protocol in which they have a conflict of interest (COI).

c. Members will sign a confidentiality agreement at the beginning of their appointment regarding meeting deliberations, SERU committee applications, information on research participants, and related matters; in addition, all SERU Secretariat staff shall sign a similar confidentiality agreement.

d. Each member shall serve for a period of three (3) years. The tenure may be renewed for one or more additional terms at the discretion of the Director KEMRI and the KEMRI Board of Management.

e. The Director KEMRI in consultation with the Board of Management shall have authority to remove or replace a SERU committee member.

f. The Director KEMRI may terminate the services of or disqualify a member of the SERU on grounds of:
   i. Misconduct.
   ii. Abuse of office.
   iii. Non-disclosure of competing interests.
   iv. Inappropriate behaviour.
   v. Unprofessional conduct.
   vi. Failure to abide by the terms of appointment.
vii. Failure to attend more than 60% of the meetings in a year.
g. A member may resign from the SERU on his/her own volition. The member shall be required to submit his/her resignation in writing at least two (02) months prior to his/her anticipated end date to allow time to fill the vacancy that will exist as a result of his/her resignation.
h. When a new member has been appointed to the SERU, an appointment letter from the Director KEMRI shall be sent to the new member. The Head of SERU or a SERU committee Secretary shall then arrange an orientation session with the new member. On completion of the induction, the new member may begin attending the SERU meetings.
i. Members will be reimbursed for expenses incurred in attending the SERU meetings and/or research site visits. The allowance shall be decided upon by the Director KEMRI and the Board of Management and may be subject to change.

**Continuing Education for SERU Members**

a. All the SERU committee members shall be asked to participate in workshops germane to the SERU committee responsibilities.
b. Each SERU committee member shall be given the opportunity to attend Bioethics and Scientific Conferences or Seminars whenever funds to support these activities are available.
c. All the SERU members shall be required to undertake ethics training, e.g. The Collaborative Institutional Training Initiative (CITI) program or a similar curriculum, at least once every three (3) years.
2.1 Application Requirements

a. All applications (SERU/SSC and NON KEMRI/NON-SSC categories) for ethical and scientific review must be submitted by the close of business on the posted closing date for each committee.

b. The SERU Secretariat shall pre-review all submitted applications for completeness. Only complete applications shall be queued for the next SERU meeting’s agenda.

c. The closing dates for receipt of proposals for ethical consideration shall be twelve (12) working days prior to each SERU meeting.

d. The dates of the meetings shall be made available at the beginning of each calendar year by the office of the Deputy Director, Administration and Finance (DD A&F), KEMRI.

e. An application for ethical review of a research study shall be made by the Principal Investigator (PI) for that study.

f. Only one application for ethical review should be made for any research study.

g. All the relevant documents listed in the Appendix (SERU Check list) must be submitted.

h. All complete applications shall be reviewed within twenty one (21) working days of receipt by the SERU Secretariat.

i. The average turnaround time from date of the meeting to final approval of a new application is estimated to be eight (8) weeks, and can be more or less, depending on the quality of the application, the nature of the proposed research and PI’s response time to the SERU’s review.

2.2 Documentation

All documentation required for a comprehensive review of the ethics of proposed research should be submitted by the PI (for NON-SSC/NON KEMRI proposals) or forwarded by the CSC Secretary for consideration.

2.2.1 The documents for ethical review include, (but are not limited to):

a. Signed and dated CSC forwarding form for KEMRI research proposals.

b. Comments received from the CSC reviewers. All issues raised by the CSC reviewers should have been addressed.

c. Any regulatory approvals: In the case of NON-SSC/NON KEMRI proposals, proof of scientific or ethics review and approval from the home institution of the PI.

d. The study protocol, with version number and date, of the proposed research. All relevant attachments like case report forms, interview guides, questionnaires, diaries, advertisement and promotional materials, focus group discussion guides.

e. All the study instruments must be translated into a language understandable to the community in which the research will be conducted.

f. The Curriculum vitae of all non-KEMRI investigators on the study (refer to Appendix E: Sample Curriculum Vitae).
g. The Informed Consent Document, including patient information sheet and Informed Consent/Assent form, local language(s) translated Consent/Assent documents and a Certificate of Translation and back translation. Translated study tools and a Certificate of Translation and back translation where applicable. (Refer to Appendix P – Translation Certificate).

h. When the research involves an investigational drug, all relevant toxicological and pharmacological data and information on the planned treatment period should be provided.

i. Evidence of current ethics training –valid for 3 years from date of completion

j. Annual Medical retention licenses for Medical personnel where applicable.

k. The specification of any medical device to be used in investigation should also be provided. In addition, the registration and import permits of the investigational drugs or medical devices must be received from the Pharmacy and Poisons Board after ethical clearance is granted by the SERU. The PPB is the Drug Regulatory Authority in Kenya. Such import permits will be granted after the Expert committee on Clinical trials (ECCT) approves the study. Investigators should check the PPB website for current requirements for submission after SERU approval.

l. The agreement to comply with the relevant national and universally applicable ethics guidelines and rules.

m. The statement describing any compensation for study participation including expenses and access to medical care to be offered to research participants.

n. The description of the arrangements for indemnity in case of study-related injuries, if applicable.

o. The description of the arrangements for insurance coverage for research participants, if applicable.

p. The statement of conflicts of interest or a statement that there is no conflict of interest.

q. Any other pertinent information to the proposed study.

2.3 Scientific Aspects

The scientific aspects of the research should include a discussion of the following:

a. The proposal should be in line with the KEMRI approved proposal format (Appendix Q: KEMRI proposal format).

b. The research problem, background analysis, question(s) and/or hypothesis.

c. The innovative nature of the proposed research.

d. The relevant literature.

e. The study objectives.

f. The research design and methodology (inclusion/exclusion criteria, study procedures, statistical validation of the sample size, study population and analytical plan for assessing results).

g. The appropriateness of the budget.

h. The roles and responsibilities of all investigators on the study.

i. The research expertise of investigators on the study.

j. The plans for capacity building and/or technology transfer in the course of the research.

k. The agreements on intellectual property issues prior to commencement of the study.

The guidelines for proposal development and scientific review are detailed in the KEMRI Proposal Document.
2.4 Ethical Aspects

The ethical aspects of the research should include a discussion of the following:

a. The recruitment plan: This should include but not limited to:
   - Identification of the potential study participants.
   - Contacting the potential study participants: Initial contact by the PI or applicant through person-to-person contact, letters, flyers and media scripts or through direct advertisement.
   - Screening procedures including administration of a test of understanding and interviews.
   - Incentives for participation in the research study.
   - Special issues related to research conducted in schools or businesses.
   - Any inducement for participation.
   - If any deception will be required for the validity of the results, the PI will be required to explain why this is necessary and a copy of the debriefing statement must be submitted with the application.

b. The potential benefit to participants, community or society.

c. The potential harm to participants and others and how these will be minimized.

d. The adequacy of provisions to protect confidentiality of data.

e. Alternative treatments or procedures available in place of study procedure

f. The adequacy of the clinical research facilities hosting clinical trials. The study site must have procedures for receipt, custody, control and dispensing of the investigational drugs or medical devices.

g. The adequacy of information for the purpose of obtaining informed, voluntary, non-coercive consent or assent.

h. The plans for dissemination or publication of results – favorable or unfavorable – while maintaining the privacy and protecting confidentiality of the study participants.

i. All significant previous decisions (e.g. those leading to a deferral or modified protocol) by other research regulatory authorities for the proposed study (whether in Kenya or elsewhere) and an indication of the modification(s) to the protocol made on that account.

j. The reasons for the deferral should also be provided.

k. The data safety and monitoring plan. This includes but is not limited to the plans for:
   - Assuring compliance with requirements for reporting adverse events;
   - Monitoring progress of clinical trials and safety of research participants;
   - Assuring that any action resulting in temporary or permanent suspension of a trial or study is reported to the SERU and relevant authorities;
   - Assuring data accuracy and protocol compliance;
   - Assuring communication and exchange of information among multi-centre sites to adequately protect study participants.
3.1 The SERU Secretariat shall prepare the agenda for each scheduled meeting.

3.2 All complete applications received by the closing date will be assigned to the agenda for consideration at the next scheduled SERU committee meeting.

3.3 Applications from KEMRI investigators must be forwarded by the CSC Secretary. Applications of the NON KEMRI/NON-SSC category should be submitted by the PI to the SERU Secretariat and will be assigned a new number successively.

3.4 The SERU Secretariat shall designate the primary reviewers for each application under SERU consideration. The primary reviewers must not have either a vested interest in the study (i.e. be named as an investigator or have a supervisory or advisory role) or a conflict of interest (i.e. be involved in the research or in research that competes with the research proposal or application under review or have a financial interest in the sponsor or the outcome of the research).

3.5 The Head of SERU/ the SERU committee Chairperson(s) or SERU Secretariat shall use their discretion for inclusion of other documents received after the deadline for submission.

3.6 The following agenda format shall be used:
   a. Attendance/Apologies.
   b. Declaration/ signing of Conflict of Interest.
   c. Confirmation of minutes of the previous meeting.
   d. Matters arising from the previous minutes.
   e. Review of new proposals or applications.
   g. Review of study status reports.
   h. Review of final study reports.
   i. Review of safety reports.
   k. Expedited review reports.
   l. Any other business.
   m. Date of the next SERU meeting

3.7. The agenda shall be prepared showing the application unique identification number and its status (e.g. new, amended, study renewal), the title of the study, the name of the PI and the name of the SERU members assigned as primary reviewers.

3.8 The SERU Secretariat will complete and close the agenda twelve (12) working days prior to the SERU meeting date.

3.9 The SERU meeting files for each SERU member attending the meeting shall be assembled by the Secretariat.
3.10 Each SERU committee member shall receive one copy of the application and any additional materials submitted with the application that he/she is assigned to present as the primary reviewer. In addition, each primary reviewer shall use the recommended format to annotate his/her issues, concerns about the research or any recommendation(s).

3.11 The agenda, including a copy of each of the items on it shall be included in the SERU meeting files and distributed to SERU members at least six (6) to ten (10) working days prior to each meeting.

3.12 **Agenda Addendum**

a. The SERU Secretariat shall create a supplementary agenda if extra items need to be added to the meeting after the agenda has been closed following consultation with the Head, SERU.

b. The SERU Secretariat shall consult with the Head, SERU regarding reviewer assignments; designate the reviewer(s) to the additional agenda items, and forward necessary documents to the SERU committee member(s).
4.1 Each SERU committee shall hold at least twelve (12) scheduled meetings in each calendar year for the purpose of scientific/ethical review.

4.2 The meeting schedule shall be established in advance and a hard copy provided to the SERU committee members at the beginning of each calendar year.

4.3 The schedule for the SERU committee meetings shall set out the dates, times, venues of meetings, and the closing date for applications to each meeting.

4.4 The SERU Chairperson(s) shall convene special ad hoc meetings, within three (3) to five (5) working days’ notice, to provide expeditious review of research proposals or applications, address concerns regarding the rights and welfare of study participants, review unanticipated problems or non-compliance issues.

4.5 The SERU members shall receive final notification of the meeting, the agenda and the SERU meeting files at least six (6) to ten (10) working days in advance of the meeting.

4.6 The minutes of each meeting shall be recorded and confirmed at the next convened SERU meeting, with the signature of the Chairperson appended on the last page of the document.

4.7 The SERU Secretariat may invite a Principal Investigator to a SERU meeting to present their proposal or to elaborate on specific issues or to offer clarifications.

4.8 The SERU Secretariat may also invite independent consultants to a meeting or request them to provide written comments upon review of an application subject to prescribed confidentiality agreements (refer to Appendix H: Confidentiality Agreement Form).

4.9 All the SERU committee meetings shall be directed by the Chairperson; if the Chairperson is not available, the Vice Chairperson or alternate shall conduct the meeting. This arrangement shall be recorded in the minutes of the meeting.

4.10 All core SERU members must be present at each meeting or must have provided their evaluation comments via the SERU Secretariat prior to a scheduled SERU committee meeting.

4.11 No SERU meeting shall be held or proceed without a quorum constituting of fifty percent plus one (50% plus 1) of core SERU members including one member from the SERU Secretariat. A quorum shall consist of one member who is a clinician, one member who is a non-clinician scientist, two members with professional training in a non-scientific area, a non-affiliated member and a lay representative.
4.12 If quorum is lost during a meeting, the SERU shall not make a decision on a research proposal or application until the quorum is restored. If quorum cannot be reestablished, the meeting shall be stopped and re-scheduled.

4.13 A SERU committee member should attend at least sixty percent (60%) of the scheduled meetings each calendar year. Failure to attend the required minimum may lead to termination of the appointment to the committee.

4.14 Attendance of a Principal Investigator

a. The SERU Secretariat shall invite a PI, in writing, to attend the meeting at which his/her application requires further clarification or discussion. The PI shall not be required to make any formal presentation of the study at the meeting, unless requested to do so ahead of the meeting.

b. The purpose of invitation shall be to enable the PI respond directly to requests from the committee for further information, clarification or reassurance.

c. The attendance of the PI shall not be prescriptive and consideration of the PI’s application shall not be biased if he/she is unable to attend.

d. The costs incurred in attending an SERU meeting shall be borne by the PI or applicant.

e. The SERU holds closed session meetings therefore the invited PI or applicant will be requested to wait outside the meeting room until he/she is called in for discussions on his/her research proposal or application. The invited PI may come along to the SERU committee meeting with any additional study team members but this arrangement must be made between the PI and the study team.

f. Where the PI is unable to attend, it shall be acceptable for another key investigator or collaborator to substitute. A representative of the sponsor shall not be eligible to attend in place of the PI, but the SERU committee Chairperson may allow this in exceptional circumstances, but must be accompanied by a key investigator.

g. Where speakerphone facilities are available in a meeting room, the SERU committee may offer the PI the alternative of a teleconference. This shall be done only when it is possible for all members present in the room to address the PI and hear his/her responses and vice versa.

h. In the case of applications submitted by students, the SERU shall consider inviting both the student and supervisor to attend a meeting.

i. All attempts will be made by the SERU committee to resolve issues of concern at the meeting.

j. When further consideration needs to be given to an application after the attendance of the PI, his/her re-attendance shall be deemed useful in formulating a conclusive decision on his/her application. However, the PI shall not be present during the confidential discussions and final assessment of their application by the committee.

4.15 Attendance of an Observer

a. An observer or observers may be invited to attend the SERU committee meetings, subject to written invitation setting out the terms under which observer status is permitted. These include: signing of a confidentiality agreement, detailing the purpose of the attendance and the concurrence of the SERU members on the meeting to be attended by the observer(s).

b. An observer or observers shall have no vested interest in the scientific or management responsibility for any applications being considered at the SERU committee meeting.
c. The Chairperson shall verbally inform any investigator who attends the meeting whenever an observer is present. The investigator shall be given the opportunity to object to or approve the presence of any observer. If there is an objection, the observer shall be requested to leave the meeting room during the discussion of that item of the agenda.

d. SERU committee meetings, or parts of meetings, may also be attended from time to time by representatives of the KEMRI administration. The arrangements for such attendance shall be discussed and agreed upon in advance with the SERU committee Chairperson and shall be subject to the terms and conditions set forth for the attendance of an observer.

e. The attendance of an observer or observers shall be recorded in the minutes.
5.1 The SERU Secretariat shall be responsible for preparing and maintaining detailed minutes of each SERU meeting.

5.2 The minutes of the meetings shall include the following items:
   a. Attendance, including members present, absent and apologies received with reasons provided.
   b. Any conflict of interest related to each protocol reviewed during the meeting.
   c. The names of SERU members who abstained from participating in the deliberations on a specific research proposal or application due to competing interests.
   d. The time meeting was initiated and closed.
   e. The approval of previous meeting minutes.
   f. The resolution of action items from the previous meeting.
   g. The KEMRI SERU/SSC number, NON KEMRI/NON-SSC number, the type of review, the title of the proposal and the PI.
   h. A summary of the proposal, the discussion and decision taken by the SERU. The views of an absent member will also be referenced.
   i. A detailed summary of the ethical and scientific issues identified and discussed in relation to a new research proposal, an amended protocol, annual or status reports, incident and adverse event reports and any other items on the agenda.
   j. The basis for requiring modification in or for disapproving research.
   k. The basis for requiring an approval period shorter than the prescribed twelve (12) months e.g. six (6) months.
   l. The approval period for initial or continuing review.
   m. The names of investigators or applicants who attended the meeting or have been invited to attend a particular SERU meeting for discussions on their research proposals or applications.
   n. The date and signature of the Chairperson.

5.3 The minutes shall be produced within ten (10) to fifteen (15) working days following the relevant meeting and shall be verified by the Secretariat.

5.4 The minutes shall be circulated to all SERU committee members as an agenda item.

5.5 The SERU committee members shall be given an opportunity to seek clarifications, request for changes or corrections to the minutes prior to adoption at the next convened SERU committee meeting.

5.6. The Minutes shall be confirmed and signed during the SERU committee meeting(s).
6.1 The SERU committee shall review new SSC/SERU and NON-SSC/NON KEMRI research proposals or applications at its next available meeting providing the complete research proposals or applications are received by the SERU Secretariat on or before the closing date.

6.2 The research proposals or applications shall be assessed by all members present at a given SERU committee meeting and by designated reviewers who have provided typed review comments in absentia.

6.3 The SERU committee shall make an ethical evaluation only on complete research proposals or applications.

6.4 Each research proposal or application requiring initial review shall be individually presented, discussed and acted upon at a convened meeting.

6.5 At least three members designated as primary reviewers, will initiate discussions on the research proposal or application, identify any scientific or ethical issues and facilitate the resolution of any issues raised on the proposal or application.

6.6 In the absence of comments from at least two designated reviewers, the Chairperson shall appoint additional reviewers to ensure the review is completed in a timely manner.

6.7 Taking cognizance of the prior scientific review (also refer to Clause 2.3), the SERU committee shall provide an assessment of:
   a. The scientific validity of the research question.
   b. The relevance of the proposed study to the health needs of the community under study.
   c. The risks to potential research participants are minimized and are reasonable in relation to anticipated benefits.
   d. The safeguards that are included to protect the rights and welfare of vulnerable research participants.
   e. Whether or not informed consent/assent will be obtained from research participants and adequately documented.
   f. The need for use of identifiable or potentially identifiable information.
   g. The level of access to information in relation to achieving the study’s objectives.
   h. The plans for collection, storage and protection of research data and/or biological samples/specimens.
   i. The provisions for compensation of research participants e.g. for their time, transport costs or lost wages.

6.8 For all NON-SSC/NON KEMRI research proposals or applications, the SERU will receive and consider the views on the research proposal held by other duly constituted Research Ethics Committees (RECs) or Institutional Review Boards (IRBs).
6.9 Following the deliberations on a given research proposal or application, the SERU committee(s) will make one of the following decisions at the meeting:

a. Approve application as submitted if all of the following conditions are satisfied:
   - The risks to research participants are reasonable in relation to anticipated benefits.
   - The knowledge that is expected to result from the research of public health or clinical importance and/or of advancement of the field of research.
   - The risks to research participants are minimized.
   - The selection of research participants is equitable.
   - Informed consent/assent will be sought from each prospective research participant and will be adequately documented, unless a waiver has been granted.
   - The research plan provides for monitoring of data collected.
   - There are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of research data.
   - There are adequate safeguards to protect the rights and welfare of research participants who are vulnerable to coercion or undue influence, where appropriate.

b. Defer making a decision on the research proposal or application until the reasons for the deferral have been addressed.

c. Defer making a decision until specialist advice or opinion has been sought and received, where applicable.

d. Not recommend ethical clearance if any of the following conditions apply:
   - The study design will mount excessive risks to research participants; or
   - The study design is flawed and will not yield generalizable knowledge of scientific merit; or
   - The value of the study results will be negligible. Thus, even though the risks may be minimal and the potential benefit almost zero, the overall risk/benefit ratio would be considered unacceptable; or
   - The study presents significant risk and asks a question that has been answered in earlier research; or
   - There is insufficient safety data on a given investigational product or device to warrant testing in any living individual.

6.10 The SERU committee(s) may at its discretion appoint an ad hoc sub-committee of three (3) persons to undertake further review of a disapproved application prior to communicating to the PI. The members of the independent sub-committee shall include at least two (2) experts in the field of research presented by the research proposal or application including one with extensive training in health research ethics, Good Clinical Practice (GCP) and/or experience in human or animal research protections. The ad hoc sub-committee shall be provided with all documents pertaining to the particular application that had been reviewed by the SERU. The review report obtained from the sub-committee shall be used in making a final decision on the proposed research study.

6.11 The SERU committee(s) shall reach a decision on the ethical suitability and feasibility of a given research proposal or application by consensus.
6.12 The SERU committee Chairperson(s) shall ensure that one of the decisions outlined in Clause 2.4 is made on every application considered.

6.13 Where unanimous decisions cannot be reached, the SERU committee(s) shall request for the provision of further information or clarification of any issue(s) by the PI or applicant, or invite the PI/applicant to attend the next convened SERU meeting. The requests for further information or clarification may include modification of the provisions of the application or any of the supporting documents such as the Informed Consent/Assent Document.

6.14 The SERU committee may delegate to the SERU Secretariat the authority to approve research proposals or applications administratively, in between meetings, if the requested clarification of information, the provision of further information, or incorporation of the requested change is satisfactory. The authority to issue any administrative approval shall be assigned by the convened SERU committee.

6.15 The Head, SERU or the Secretariat shall grant approval to an application previously discussed at a convened SERU committee meeting, when in compliance with the requirements of the SERU committee(s), within six (6) working days of receipt of a satisfactory response from an investigator or applicant.

6.16 The Head, SERU/the Secretariat shall report all approvals that have been granted at the next convened SERU meeting and the update shall be recorded in the minutes.

6.17 Any research proposal or application under SERU review shall remain on the agenda for no more than ninety (90) days i.e. three (3) consecutive scheduled SERU committee(s) meetings.

6.18 Following approval of a study for a term of twelve (12) months, the PI shall be advised to submit an annual study report (Appendix A: Sample Annual or Status Report) six (6) weeks prior to the date of expiry of the current approval and no later than the deadline for the SERU committee meeting preceding the twelve month anniversary of the date of approval.
Informed consent is a continuous process that starts with the researcher’s first contact with the individual (18 years of age and above) and continues until the study is complete or the participant withdraws. Any discussion of informed consent with the participant, the written informed consent form (Appendix F: Format and Content of an Informed Consent Document) and any other written information given to participants should provide adequate information to enable the individual make an informed choice about his/her participation.

7.1 Requirements of Informed Consent

a. The SERU shall require investigators to obtain informed consent from each prospective study participant unless it waives some or all of the elements of informed consent. Consent should be sought from adults [age eighteen (18) years and above and from parent/guardian whose child is aged seventeen (17) years or below if the child will be involved in a research study].

b. A full description of the process for obtaining informed consent including the identification of those responsible for obtaining consent.

c. Provision for comprehensive (without technical terms) written and verbal information to be given to the research participants, and, when appropriate, their legally authorized representative(s).

d. A clear justification for the plan to include individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.

e. Provisions within the study that research participants will receive information that becomes available during the course of the study relevant to their participation.

f. Provisions made for receiving and responding to enquiries, concerns or complaints from research participants or their representatives prior to and during the course of a research study.

g. The SERU committee shall waive all or part of the requirements for documentation of informed consent, and oral consent may be obtained, and documentation that oral consent was obtained maintained if the research meets the following criteria:

- The justification for the waiver is valid; the signed consent is the only record linking the study participant to the research and is the primary risk of breach of confidentiality by the research.
- The proposed plan for the protection of privacy is adequate.
- The waiver will not affect the rights and welfare of the research participants.
- The research participants will be given additional pertinent information after their participation.
- The research presents no more than minimal risk and involves procedures for which consent would not normally be obtained outside the research context.

h. Translation of all consent documents into Kiswahili and/or relevant local dialects. Each translated Consent Document must be accompanied by a Certificate of Translation and back Translation.
7.2 Requirements of Informed Assent

Where a proposed participant is a minor [aged thirteen (13) to seventeen (17) years of age] who is possessed of sufficient understanding to grant informed consent but is precluded from granting such consent solely on the grounds of age, the PI shall obtain a written assent in addition to permission from a parent, guardian or any person in loco parentis.

The SERU committee shall consider the following elements in its review of the assent process:

a. The procedures put in place for obtaining parental or guardian permission (consent) to have his/her child or children participate in the research. For those minors between the thirteen (13) to seventeen (17) years of age, the language and syntax of the assent form may be written in a similar fashion as the parental or guardian permission form.

b. If the research proposed is determined to present greater than minimal risk and there is no direct benefit to an individual study participant, then parental permission from both parents/guardians shall be required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

c. The parental permission and child assent is done in writing unless the SERU committee grants a waiver of documentation.

d. The table below should be used as a guide in deciding whether or not to enroll a child, aged thirteen (13) to seventeen (17) years, in research.

<table>
<thead>
<tr>
<th>If Parent Says (YES/NO) to participate</th>
<th>If Child says YES/NO to participate</th>
<th>Can Child participate</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

e. The ethical standards required in obtaining informed consent shall apply to assent. (Clause 7.2)

f. The SERU committee shall waive the requirement for obtaining assent from a child if any of the following conditions apply in which case, consent from the parent(s) is sufficient:
   - The intervention stands to directly benefit the health and welfare of the child and is available only in the research setting.
   - The child is unable to provide assent due to age [twelve (12) years of age and below] or has a condition that does not allow them to give assent.
   - The research meets the same conditions for a waiver of informed consent in research involving adults.

7.3 Obtaining Consent from a Mature Minor

a. The SERU committee shall consider a mature minor as any individual less than eighteen (18) years of age who is married, pregnant, a mother or a household head. The mature minor must
demonstrate evidence of clear understanding of the requirements for the research they are consenting to participate in

b. A mature minor is permitted to give consent for him or herself and for their child/children but not allowed to consent on behalf of a sibling.

**Under special circumstances e.g. orphaned, street children a mature minor may sign consent on behalf of a sibling.**

### 7.4 Community Considerations

During the evaluation of a research proposal or application, the SERU shall consider the following issues:

a. The potential impact and relevance of the research on the concerned communities from which the research participants are drawn.

b. The steps taken to consult with the concerned communities during the course of conducting the research and in disseminating research findings are transparent.

c. The measures taken to preclude the influence of the community on the consent of an individual.

d. The proposed community engagement process including public barazas, permission from the community elder or persons acknowledged as community representatives and where applicable, the establishment of a Community Advisory Board (CAB).

e. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare systems and the improved capability of the community to respond to their health needs.

f. The provision for making available of any successful trial product to the participating communities on completion of the research and sustainability of any intervention.

g. The manner in which the results of the research will be made available to the research participants and the concerned communities.

h. The consideration for cultural sensitivities and concerns.

### 7.5 Obtaining Consent from Special Populations

a. The SERU committee shall require that exceptional consideration is given to protecting the welfare of particularly vulnerable groups, such as children, pregnant women, neonates, foetuses, homeless youths, decisionally impaired persons, internally displaced persons, economically or educationally disadvantaged persons, marginalized social groups or individuals with terminal illnesses or prisoners.

b. In its assessment of research involving vulnerable groups, the SERU shall require that:

- The objective of the proposed research is to obtain knowledge relevant to the health needs of the population under study.
- The PI demonstrates that the research question cannot be answered if the study is carried out among a less vulnerable group.
- The study participants are explicitly told that they are taking part in research.
- The requirements for obtaining and documenting consent are tailored to the needs of the individual from the chosen vulnerable group. i.e. use of appropriate language, content of the consent/assent document and explanation of the procedures to be followed.
• The risks from procedures that do not proffer direct health-related benefit are justified by the benefit and are similar to those from routine medical or psychological tests.

c. The SERU committee shall determine on a protocol-by-protocol basis the specific requirements for obtaining and documenting consent whenever any vulnerable groups are involved in research studies.

7.6 Documentation of Consent

a. The SERU committee shall require that informed consent be documented by use of written approved consent form unless a waiver is issued subject to conditions laid out in Clause 7.1 (g).

b. The consent form must be signed and dated by the research participant or research participant’s legally authorized representative at the time of consent.

c. A copy of the signed and dated consent form should be given to the person(s) signing the consent form.

d. When verbal consent is obtained from the research participant or research participant’s legally authorized representative, the SERU committee shall require the presence of a witness to the oral presentation. The SERU committee shall review and approve the written summary of what is to be presented. This summarized approved version of the consent form should be signed by witness and the person actually obtaining the consent.
8.1 An amendment is defined as any change to a SERU approved research project, such as:
   a. Recruitment - number of study participants, recruitment methods, recruitment materials, selection of study participants etc.
   b. Research personnel - PI, Co-PI, students or research coordinators or other investigators on the study.
   c. Research sponsor or funding agency.
   d. Study site(s).
   e. Study design including but not limited to study population, methodology, study procedures, sample size, equipment, intervention or follow-up procedures.
   f. Privacy of information or confidentiality of research participants.
   g. Data collection, storage, custody or destruction procedures. This includes revisions to approved questionnaires/surveys or development of a new questionnaire/study instrument.
   h. Informed consent/assent- forms, procedures, new or additional information.
   i. Terms of compensation.
   j. Conflicts of interest(s).

8.2 All principal investigators (PIs) shall be required to submit any proposed changes to a previously approved study to the SERU committee(s) for review prior to initiation. The only one exception to this rule shall specifically be where the change is necessary to eliminate apparent immediate danger/risk to the research participants. In such instances, the principal investigator must submit a report/notification to the SERU committee explaining the protocol deviation.

8.3 All requests for a protocol amendment for all approved KEMRI-affiliated studies shall be forwarded to the SERU committee, by the CSC Secretary, for its consideration.

8.4 The request for amending any NON-SSC/NON KEMRI approved studies should be addressed to the Head, SERU and submitted to the SERU Secretariat.

8.5 The PI shall be required to submit the amended protocol, a cover letter outlining the nature of the suggested changes, the justification for the change, the amendment form and must have made an evaluation of any ethical consequence arising from the proposed amendment.

8.6 The SERU committee members assigned to review a particular amendment proposal shall be provided with the following documents:
   a. A duly signed explanatory cover letter from the PI and the amendment submission form
   b. The modified study documents highlighting the changes (“tracked changes”) and a copy of the same version of the document with incorporated changes (the “clean copy”).
   c. Any additional documents provided by the PI.

8.7 The complete application for the amendment shall be discussed at the next available SERU meeting provided that the request has been received by the deadline for submission.
8.8 The SERU committee shall determine whether the amendment is approved as submitted or if further information, clarification or change is required for the evaluation of the suggested amendment and clearly articulate the basis for such a decision to the PI or applicant.

8.9 The SERU Secretariat shall communicate to the PI, in writing, the outcome of the SERU committee deliberations on the request within six (6) working days of the meeting at which the request for the amendment was considered.

8.10 The SERU committee discussions on the amendment request shall be minuted.

8.11 The Chairperson shall expedite the review of an amendment to an approved protocol if any of the requirements set out in Clause 9.3 and 9.4 apply.
SOP 9: EXPEDITED REVIEW AND QUICK TURNAROUND

An expedited review request should be no more than minimal risk*, or a modification of an approved no more than minimal risk study, or a minor modification of a greater than minimal risk approved protocol. A quick turnaround review request is an application or proposal that requires a faster than usual review due to a major public health concern e.g. an epidemic.

*Minimal risk: the probability and magnitude of discomfort or harm anticipated in a given research that is no greater than those typically encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples include, document reviews, left over samples, anonymous samples.

9.1 The PI or applicant shall be required to submit ten (10) copies of the application (one of which has the original signature) and 10 copies of the Expedited Review form.

9.2 The SERU secretariat shall evaluate each application for its eligibility for expedited review upon request by the PI or applicant.

9.3 Only applications which meet any of the following criteria shall qualify for expedited review:
   a. New minimal risk protocols; or
   b. Modifications of minimal risk studies; or
   c. Minor modifications of greater than minimal risk studies.

9.4 The SERU shall expedite the continuing review of minimal risk studies previously approved by the convened committee provided that any one of the following conditions applies:
   a. Data analysis, report writing or manuscript preparation are the only ongoing research activities; or
   b. There is no screening and/or enrollment of new study participants; or
   c. All study-related interventions are completed; or
   d. The research is active only in the follow-up phase; or
   e. No study participants have been enrolled and no additional risks have been identified.

9.5 The secretariat shall review and also nominate at least two (2) SERU members to undertake the expedited review of the application. Should the application be approved by the expedited review team the Chairperson shall grant provisional approval.

9.6 The provisional approval granted by the Chairperson shall be subject to ratification at the next scheduled SERU meeting.

9.7 Any application that does not meet the criteria set out in Clause 9.3 shall not be evaluated under the expedited review process.

9.8 Quick Turn Around review Request
A quick turnaround review request is an application or proposal that requires a faster than usual review due to a major public health concern e.g. an epidemic (Such as Ebola, Cholera, Rift Valley Hemorrhagic Fever, Polio, Avian Flu etc.).

a. The PI should notify the Head SERU /Secretariat by phone and e-mail of the intention to submit a protocol for quick turnaround review.

b. A minimum of 6 reviewers shall be assigned to review the proposal.

c. The investigators shall submit a hard and soft copy of a complete application to SERU

9.9 The expedited review process and quick turn around shall take no longer than six (6) working days.

9.10 The PI shall be informed of the decision, in writing, within three (03) working days of receipt of all reviewers’ comments or the date of final approval following ratification of the provisional approval by the full committee.
10.1 The SERU committee shall undertake continuing review of each approved study at least once a year, but may require more frequent reviews, such as, where this is warranted by the level of risk the research presents.

10.2 The request for continuing review shall comprise a duly signed explanatory cover letter, the annual or status report, one copy of the current approved study documents any publications and/or abstracts (CRR submission form).

10.3 All active or open studies must be renewed including:
   a. A study that is closed to accrual of research participants but is in the follow-up phase.
   b. A study in which direct contact with study participants is complete but data analysis, report writing or manuscript preparation are the only ongoing activities.
   c. A proposed study that has not been initiated within twelve (12) months from the date of ethical and scientific approval provided that valid reasons for not undertaking the research in the initial approval period have been provided.

10.4 The study reports shall be reviewed at the next available SERU meeting provided that the request has been received by the deadline for submission.

10.5 The continuing review shall be substantive and the same criteria for initial review will apply (refer to SOP 6: Review of research applications).

10.6 If the continuing review does not take place within the timeframe set by the SERU committee, the research study will automatically expire. The PI shall be required, to immediately submit a list of research participants for whom the postponement of research would cause harm within five (5) days of expiration. In addition, the PI should also submit a protocol deviation form. The Chairperson in consultation with the SERU committee members shall issue an appropriate course of action. The PI may resume the study once continuing review and approval by the SERU committee has taken place.

10.7 The SERU committee(s) discussions on the continuation requests shall be minuted.

10.8 The SERU committee(s) shall determine whether further information, clarification or change is required for the evaluation of the report and clearly articulate the grounds for this decision to the PI or applicant.

10.9 The SERU Secretariat shall communicate to the PI, in writing, the outcome of its deliberations on the request within six (6) working days of the meeting at which the request was discussed.

10.10 Any given research study will be renewed at least once every twelve (12) months for the duration which was approved for the given study.
10.11 All approved research protocols shall have a life span of sixty (60) months after which a new research proposal should be developed and submitted for review or an extension be submitted with appropriate justification. A final study report should be submitted and notice of closure must be issued on or before the expiry date of approval at month sixty (60). The SERU committee shall make special consideration for research that is designed for longer study period as indicated in the approved study documents.
SOP 11: RESEARCH INVOLVING GENETIC STUDIES

11.1 The SERU committees shall review new proposed genetic-based studies at its next available meeting providing the research proposals or applications are received by the SERU Secretariat on or before the closing date.

11.2 The SERU committees shall consider genetic research as any research conducted by investigators for the sole purpose of generating scientific knowledge about genes and/or the genetic basis of disease. This may include:
   a. DNA diagnostic studies that determine the presence of specific mutations.
   b. DNA-based diagnostic tests that identify genes associated with specific medical conditions.
   c. Pedigree studies that investigate the inheritance of a particular trait or condition among related individuals or obtain information on family medical histories.
   d. Positional cloning studies that identify the location of specific genes.
   e. Gene therapy.

Requirements
For the evaluation of genetic-based research application, the PI or applicant shall be required to:
   a. Clearly define the nature and scientific justification for the proposed study.
   b. Describe all planned study activities including: recruitment procedures, eligibility criteria etc.
   c. Clearly describe the statistical considerations.
   d. Identify the risks and the known nature of the risks of the proposed genetic research, explain how the risks will be minimized, especially privacy and confidentiality protections measures to be put in place.
   e. Justify his/her choice of population from which the study participants will be drawn. When vulnerable populations will be recruited into the study, the PI/applicant must provide an explanation as to why it is critical to conduct genetic research on these individuals.
   f. Explicitly describe the genetic component of the study and the risks of the genetic analyses in the informed consent document and in the process of obtaining consent (refer to Appendix G: Format and Content of an Informed Consent Document for Genetic Studies for consent document recommendations).
   g. Disclose all persons who would have access to identifiable data of study participants and whether the results of the analyses will be released to participants or others (e.g. physicians, parents, guardians).
   h. Inform the SERU committees and research participants each time genetic analyses not only have implications for the relatives of the individuals undergoing testing, but for a community they may be identified with.
   i. Ensure that adequate measures are in place for familial research so that study participants do not recruit other family members for the research or share confidential information amongst family members without explicit consent.
   j. Provide a detailed description of the agreements between the investigators (local and international collaborators) made on access to and ownership of genetic information, findings or patents.
k. The provisions of benefit sharing with the community in which the research is conducted in terms of local training, technology transfer, improvement of health care and information infrastructure.

l. Disclose the results of the findings to research participants or their representatives who requests for the results or if it is part of clinical care of those individuals. If results will be shared with the research participants or others, the PI/applicant should discuss the following in the application:
   i. How research participants would benefit from the research results.
   ii. How predictive the tests are of the condition, disease, or genetic trait.
   iii. Whether the testing is available outside of the research context.
   iv. The measures in place to help ensure that the study results are contextualized appropriately for the study participant to understand and they have resource (e.g. genetic counselling) available to them should distress or anxiety occur associated with the research and the study results obtained. The expertise of the study staff responsible for educating and counselling research participants regarding the risks and benefits of the study must be clearly demonstrated in the curriculum vitae.
   v. Disclose whether or not the genetic information will be placed in a medical record.

m. Use of genetic material:
   The PI or applicant will be required to:
   i. Describe the procedures to be used to obtain samples including the type, amount and/or size of tissue sample(s) to be taken.
   ii. Provide an explanation as to whether or not identifying information will be maintained and how confidentiality will be assured.
   iii. Describe how the issue of sample/storage failure will be handled; if re-contact will/might be made for additional samples.
   iv. Describe the procedures the study participant will use to request that their sample/cell line be destroyed or stripped of identifiers; Specify how samples will be coded.
   v. State explicitly (if applicable) whether or not samples may be used for research purposes, if that is the case, but will remain coded and anonymous to the research and characterize what these other uses may be.
   vi. State whether or not samples may be shared with third parties but will be sent out coded and remain completely anonymous to the third party, if applicable.

**Genetic Testing**
When proposed research involves genetic testing, the SERU committee will consider the following factors in making a determination of level of risk presented by the research:

a. The procedures for the use of identifiable samples.

b. The plans, if any, for storage and future use of samples.

c. The plans for release of test results: Information families will receive and at what stage of the study; how study results will be handled; and whether individuals will be given an opportunity not to receive information about themselves.

d. The involvement of a vulnerable population and what information will be provided and when;

e. The procedures for obtaining informed consent; how the implications of the findings will be handled; what support services will be available; the plans for protecting confidentiality; plans for handling psychological or social issues.
f. The condition/trait under study – if testing is done on the genetic basis of a condition already known to be exhibited by the research participant (e.g. breast cancer), then the risks may be lessened.

g. The potential for incidental findings: e.g. paternity or information obtained through linkage among genes such that a condition, disease or trait not under study could be discovered.

h. The SERU committee's discussions on the research proposal or application shall be minuted.
12.1 The SERU committee is designated by KEMRI to approve the initiation of and perform periodic review of all research conducted in the institute. This includes studies involving animals.

12.2 The SERU committee shall review new research proposals or applications involving animals at its next available meeting provided the research proposals or applications are received by the SERU Secretariat on or before the closing date.

12.3 Any application for research involving animals will be approved by SERU only after Animal Care and Use Committee (ACUC) approval is granted and on submission must include:
   a. Five (5) copies of the study protocol and any supporting documents to SERU,
   b. A copy of the ACUC approval letter,
   c. Evidence of prior scientific review and approval by a duly constituted scientific review and/or ethics review board e.g. The IRB approval letter for NON-KEMRI-based studies,
   d. CVs of veterinary experts, animal care staff and of all NON-KEMRI affiliated investigators on the study.

12.4 In its review, the SERU shall make an assessment of:
   a. The justification for the use of animals.
   b. The arguments in support of the chosen animal species or model.
   c. The training and expertise of veterinarians and animal care staff on the study.
   d. The biosafety measures instituted in all aspects of the study.
   e. The potential benefits and harms presented by the study and the possibility of reducing the harms.

12.5 The SERU committees’ discussions on the study protocol or application shall be recorded in the minutes.

12.6 The SERU Secretariat shall communicate to the PI, in writing, the outcome of its deliberations on the proposed animal study (or on any amendments to an approved animal study) within six (6) working days of the meeting at which the research proposal or application was discussed.
13.1 The Head, SERU will inform the PI, in writing, the outcome of proposal review within six (6) working days of the meeting at which the decision was made.

13.2 The letter sent to the PI or applicant should explain the reasons for the decision and point out the required information.

13.3 If the requested information for new applications is not received by the SERU within ninety (90) days [usually three (3) consecutive SERU committee meetings], the research proposal will be removed from the agenda and the investigator will be required to resubmit the proposal for review at the CSC meetings. The PI or applicant and the CSC Secretary shall be informed, in writing, of the decision.

13.4 The SERU committees and the secretariat shall encourage open communication with investigators to resolve outstanding requests for information, modification, and clarifications of issues raised on a particular proposal or application.

13.5 Any appeals to the SERU decision of disapproval or denial of ethical clearance to a proposed research study shall be handled as laid down in SOP 22: Handling Appeals of SERU Decisions.

13.6 The letters for notification of approval shall include the following information:
   a. The SERU/SSC number or NON-SSC/NON KEMRI number.
   b. The name of the investigator and institutional affiliation.
   c. The exact title of the research proposal or application.
   d. All documents reviewed by the SERU including the date and version numbers of each document.
   e. The date and the SERU meeting at which the research proposal or application was discussed.
   f. A summary of the objective of the proposed study.
   g. The date approval was granted.
   h. The duration of the approval.
   i. The requirement that the research proposal or application must be carried out as stipulated in the proposal or application.
   j. The requirement that any changes to the research study or its conduct be reported to the SERU committees prior to initiation.
   k. The requirement that any unanticipated adverse events that might affect continued approval of the study or if the study is terminated for any reason it should be reported to SERU.
   l. The requirement for the PI or applicant to apply for new review and approval for substantially modified or revised research protocols.
   m. The requirement for the submission of an annual study report and a final report at the completion of a study.

13.7 The letters for notification of deferment shall include the following information:
   a. The SERU/SSC number or NON KEMRI/NON-SSC number.
   b. The name of the investigator and institutional affiliation.
c. The exact title of the research proposal or application.
d. All documents reviewed by the SERU including the date and version numbers of each document.
e. The date and SERU committee meeting at which the research proposal or application was discussed.
f. A summary of the objective of the proposed study and key study activities.
g. The requirement for the PI or applicant to provide additional material or information to undergo review. The supplementary materials may include data collection sheet, sample patient diaries, study instruments, CVs, supporting literature etc. if applicable.
h. The requirement for changes in the Informed Consent/Assent Documents or in the body of the study protocol, if applicable.
i. The Head, SERU/SERU Secretariat shall detail the required changes and also outline any additional information or clarification on specific issues necessary for the SERU to make its final decision. The SERU Secretariat shall do this on one occasion, followed by two (2) reminders. The ninety (90) days response period shall start from the date the initial letter was sent to the PI. The clock starts again on the date a complete response is received.

13.8 The letters for notification of disapprovals shall include the following information:
a. The SSC/SERU number or NON-SSC/NON KEMRI number.
b. The name of the investigator and institutional affiliation.
c. The exact title of the research proposal or application.
d. All documents reviewed by the SERU including the date and version numbers of each document.
e. The date and SERU committee meeting at which the research proposal or application was discussed.
f. A summary of the objective of the proposed study and key study activities.
g. The SERU Secretariat shall describe to the PI or applicant the basis for the disapproval and any modification to the research proposal or application that would be required for the SERU to re-consider its views on the proposed study. The CSC Secretary shall also be notified of the disapproval.
h. The Head, SERU/Secretariat shall also explain to the PI or applicant that he or she may request the SERU committees to consider a new application if additional information becomes available or if changes are made to the proposed study that would address the SERU’s initial concerns.

13.9 Dispatch of correspondence to a PI
a. The letters shall be signed by the Head, SERU. However, the SERU committee Secretary (ies) may be authorized to sign letters on behalf of the Head, SERU.
b. Three (3) copies of each letter shall be produced. Two (2) of the letters shall be sent to the respective Centre Directors for forwarding to the relevant PIs and for the Centre records. One (1) letter shall be filed in the appropriate research study file.
c. The letter shall request a response from the PI or applicant within twenty (20) working days from the date of the letter. Two reminders (initial and final) shall be sent to the PI, after which a notice of removal of the item from the SERU agenda shall be sent to the PI, who will be required to resubmit a new application.
d. The letter shall request that the PI or applicant directs his or her responses to the Head, SERU.
e. The PI or applicant will be requested to resubmit two (2) copies of the revised proposal or application and other study documents requested if the proposed study was deferred.

13.10 Handling a response from a PI or applicant

a. A response from a PI shall include a duly signed explanatory cover letter, the revised research proposal highlighting the revisions made or any additional information, if applicable.

b. Upon receipt of a response from the PI, the SERU committee Secretary and/or SERU committee Assistant Secretary shall review the response to determine if all revised or new documents have been received and each question raised by the SERU has been adequately addressed.

c. If the PI or applicant disagrees with the SERU’s interpretation or request, then he/she should explain his/her reasons in writing. The response will be reviewed by the secretariat and if necessary the response will be included in the next available SERU meeting’s agenda for further review.

d. Where outstanding issues have been resolved or adequately addressed, the SERU Secretariat shall proceed to issue an approval as agreed upon earlier by the convened SERU committee meeting. The approval shall be reported at the next convened SERU meeting.

e. If a research proposal or application had been deferred, the response will be reviewed and included in the next available SERU agenda if necessary, for further review. The PI may be requested to attend an SERU meeting for further discussions. The decision on a PI’s attendance shall be decided upon at a convened SERU meeting.

f. If a study had not been granted ethical clearance and the PI would like to appeal, the procedure in SOP 22 shall be followed. All responses from a PI or queries shall be acted upon with six (6) working days of receipt by the SERU Secretariat.
**SOP 14: REQUIREMENT FOR CLOSING A RESEARCH STUDY**

A PI shall be allowed to file a close-out report with the SERU after:
- Publication of the main manuscript
- All participant recruitment and follow-up has ceased; or
- All study samples have been collected; or
- Data has been locked

14.1 The close-out report shall be reviewed at the next available SERU committee meeting provided that the notification has been received by the SERU Secretariat on or before the closing date for submission.

14.2 The SERU committee shall review the following items of a study close-out report:
   a. The summary of all research activities clearly demonstrating that all study activities including follow-up procedures are completed (Appendix I: Closure report).
   b. The study results and dissemination reports.
   c. Copies of any publications arising from the study.
   d. The plan (or not) to refer back to the medical records to verify research data, if applicable.
   e. An assurance of the destruction of each study participants’ identifiers, whether direct or indirect (provide a copy of blacked out pages of the screening and enrolment logs).
   f. An assurance that any surplus investigational agent has been destroyed.
   g. An assurance that any surplus biological specimens has been destroyed unless the study protocol stipulated that the specimen(s) in question would be subject to long term storage and future research.

14.3 The SERU committee shall evaluate the close-out report and inform the PI in writing within six (6) working days of the meeting at which the report was discussed.

14.4 All closed study files shall be retained in the SERU Office for three (3) years from the date of closure, upon which the files shall be indexed, boxed, and sent to the SERU archives.
15.1 The SERU charges a fee for the review of NON-SSC/NON KEMRI proposals in line with guidance from NACOSTI and as approved by the KEMRI Board of Management.
16.1 The SERU shall require the reporting of any adverse events noted during the conduct of a study.

16.2 The SERU shall consider an adverse event as any unfavourable sign, symptom or disease, including an abnormal laboratory finding regardless of whether or not it has a causal relationship.

16.3 A serious adverse event is any untoward medical occurrence that:
   a. Results in death.
   b. Is life-threatening.
   c. Results in persistent or significant disability or incapacity.
   d. Requires inpatient hospitalization or prolongation of existing hospitalization.
   e. Is a congenital abnormality or birth defect.
   f. Requires intervention to prevent permanent impairment.

16.4 Any study-related unexpected or serious adverse event must be reported to the SERU via email (seru@kemri.org/serukemri@gmail.com) within forty eight (48) hours after the PI becomes aware of the event. The hard copies of the report must be forwarded to the SERU Secretariat within five (5) working days of the initial notification. Follow-up reports should be submitted as soon as more information becomes available.

16.5 Any study-related expected adverse event or adverse events not related to participation in the study must be reported by the PI, in writing, within ten (10) working days after the investigator becomes aware of the event (refer to Appendix C: Sample Adverse Event Reporting Form). However, if the PI notices that the expected adverse events are occurring with greater frequency than anticipated or a higher level of severity than expected, then the reports must be submitted within three (3) working days.

16.6 The written safety report should be addressed to the Head, SERU and submitted to the SERU Secretariat office.

16.7 The reporting should include the presumptive diagnosis and the PI’s opinion on the relationship of the adverse event with participation in the study.

16.8 The SERU committee(s) shall review the adverse event at its next scheduled meeting at which a determination shall be made on the appropriate course of action. The appropriate action may include:
   a. Request for an amendment to the approved protocol.
   b. Request that additional information regarding risks be given to the research participants.
   c. Increased surveillance of the study.
   d. Further investigation of the event by a SERU member or external expert.
   e. Suspension of ethical and scientific approval.
   f. Termination of ethical and scientific approval.
   g. Note the occurrence.
16.9 The PI shall be required to submit a follow-up report if the information received suggests that the severity of an event has increased, or suggests the event is more likely to be related to the study than initially thought, or seems to affect the rights and welfare of current study participants.

16.10 The SERU committee shall also review external adverse events whenever reported by a local investigator. The external adverse events shall typically be reported by an external investigator and describes adverse experiences by study participants engaged in a multi-centre or multi-country clinical trial in which KEMRI is one of the participating trial sites.

16.11 The SERU committee shall communicate to the PI, in writing, its decision or its intention to take a particular action within five (5) working days of the date at which the decision was made.

16.12 The following definitions of the relationship of an adverse event with an investigational agent or procedure are issued as a guide

- **Not related**: The adverse event is clearly not related to the investigational agent or procedure. Another cause of the event is plausible.
- **Unlikely related**: The adverse event is uncertainly related to the investigational agent or procedure.
- **Possibly related**: The event follows a reasonable temporal sequence from administration of the study drug or procedure, follows a known or expected response pattern to the suspected drug, but that could readily have been produced by a number of other factors.
- **Probably related**: The adverse event is likely related to the investigational agent or procedure.
- **Definitely related**: The adverse event is clearly related to the investigational agent or procedure i.e. the event follows a reasonable temporal sequence from administration of the study drug, follows a known or expected response pattern to the suspected drug, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and the event could not be reasonably explained by the known characteristics of the patient’s clinical state.
17.1 The SERU shall consider a protocol deviation as any failure to adhere to the defined study procedures or treatment plans outlined in the protocol version previously approved by the SERU.

17.2 The SERU shall consider a protocol violation as any planned or inadvertent changes that may or may not impact safety of study participants, affect the integrity of study data, and/or affect study participants’ willingness to participate in the study previously approved by the SERU.

17.3 The reporting should be made in writing, addressed to the Head SERU and must be received in the SERU office within ten (10) working days of the deviation or violation.

17.4 The SERU committee shall review the deviation or violation report (Appendix D: Sample Protocol Deviation or Protocol Violation Reporting Form) at its next scheduled meeting, at which a determination will be made on the appropriate course of action or the incident will be noted if the remedial measures taken by the PI are satisfactory and appropriate.

17.5 The SERU Secretariat shall communicate to the PI, in writing, the decision of the SERU committee or its intention to take a particular action within six (6) working days of the meeting at which the decision was reached.
18.1 The SERU shall monitor the progress of all research for which it has granted scientific and ethical clearance to ensure it is in compliance with conditions of approval and the ethical rules and principles contained in the national guidelines and SERU Standard Operating Procedures.

18.2 The SERU may at any time request and discuss information on any pertinent aspect of the research study with the PI and study team members.

18.3 The SERU will require investigators to provide an annual report, and a final report at the study’s completion. Continuing approval of the research will be dependent on the investigator’s submission of an annual report (Appendix A: Sample Annual or Status Report).

18.4 To ensure that research progress for any study is monitored at least once a year, study reports should be received in time for consideration by the SERU at least six (6) weeks prior to the expiration date and no later than the meeting preceding the twelve (12) month anniversary of the date of the ethical approval. For example, for a research study granted ethical approval late November 2015, the annual report should be received by the closing date for the meeting preceding the meeting to be held at the end of November 2016.

18.5 The SERU may at any point adopt the following mechanisms for monitoring as deemed necessary:
   a. Request for frequent progress reports from a PI.
   b. Request for a meeting with the PI.
   c. Random inspection of research sites.
   d. Random examinations of research records, including signed informed consent documents, protocol modifications, reports of unexpected and/or serious adverse experiences and sample shipment logs.
   e. Make contact with research participants.

18.6 The SERU shall monitor the following studies:
   a. Clinical trials of investigational medicinal products, medical devices or any other new entities.
   b. Studies which report significant unexpected adverse events or serious adverse drug reactions in a number that is determined by the SERU to require frequent assessment.
   c. Studies with multiple arms or multiple and/or complex study procedures.
   d. Studies that involve consenting vulnerable groups.
   e. Studies investigating alternative therapies.
   f. Studies involving the collection, use and retention of human tissue samples for research purposes.
   g. Studies involving critically ill patients.
   h. Studies involving animals.
   i. Studies conducted by investigators who have previously failed to comply with KEMRI and/or national research regulations and/or GCP guidance.
18. 7 The SERU may also schedule a site audit visit at its discretion.
19.1 SERU shall have the authority to suspend ethical approval for any research where it is of the opinion that the research is not being or can no longer be conducted in accordance with provisions of the approved protocol. The Head SERU shall then inform the Director KEMRI of this decision.

19.2 SERU may also suspend the ethical approval of a research study when there is any serious non-compliance with applicable research regulatory requirements.

19.3 The committee Chairperson shall request, in writing, for an immediate, temporary suspension of enrolment of new study participants or of continued participation of previously enrolled study participants, pending review of the situation at the next scheduled SERU meeting(s).

19.4 The convened SERU committee(s) shall review the suspension report. The actions SERU may take include (but are not limited to):
   a. Require minor or major changes in the research procedures and/or consent documents or process.
   b. Modify current approval period.
   c. Require monitoring of the research.
   d. Require monitoring of the consent process.
   e. Suspension of enrolment of new study participants.
   f. Require notification of the enrolled participants when such information may influence their willingness to continue participating in the research.

19.5 SERU shall assign reasons for its action and promptly advise the PI and study sponsor, in writing, of such suspension and the necessary steps to be taken.

19.6 The suspension shall occur within six (6) working days of the date the SERU makes the determination and no later than five (5) working days after the PI has received the notice of suspension.

19.7 SERU shall notify the PI immediately upon determination that there is increased risk.

19.8 The SERU committee will lift the suspension of a suspended study after determining that all the issues raised have been adequately addressed.
20.1 The SERU committee shall have the authority to terminate the approval of any research for which it has granted clearance when:

a. There is **gross misconduct** by a PI or any investigators on the study that is evidently confirmed.

b. The research presents excessive risks to research participants i.e. the actual risk-benefit status of the study is not consonant with the predicted risk-benefit ratio prior to implementation of the study.

c. A PI or study team members fail to comply with research regulations.

20.2 The Committee Chairperson shall request an immediate termination of further accrual of new study participants or of continued participation of previously enrolled study participants whenever any of the conditions outlined in Clause 20.1 apply.

20.3 The committee Chairperson shall convene a special meeting at the earliest convenience to review the termination report. The actions the SERU may request for include (but are not limited to):

a. A summary of the study protocol and the accrued data.

b. Submission of the study results at the time of termination.

c. Establishment of a mechanism for an extended follow-up to monitor safety issues.

d. Require the PI to debrief study participants of the termination and also notify those study participants who have completed study activities.

e. Compensation of study participants, where applicable.

f. A requirement that the principal investigator and the study team members undertake health research ethics and GCP re-training.

g. Perform an audit of other active studies of the principal investigator.

20.4 The SERU committee shall give reasons for its action and advise the PI and study sponsor, in writing, of such termination and the measures needed.

20.5 The termination shall occur within six (6) working days of the date the SERU committee makes the determination and no later than five (5) working days after the PI has received the notice of termination.

20.6 SERU shall notify the PI of the unacceptable increased risk to the participants within six (6) working days.

20.7 The PI shall not resume a terminated study.

20.8 The Committee Chairperson shall inform the study sponsor, the Director KEMRI and the, Chair and Secretary of the National Bioethics Committee (NACOSTI) and where relevant the OHRP of the termination or withdrawal of any ethical approval.
21.1 The Head of SERU shall handle all complaints regarding the conduct of a research study.

21.2 The position and contact information of the Head SERU shall be included in all Informed Consent/Assent Documents for all studies.

21.3 Any individual with a complaint about the conduct of a study will be required to notify the Head SERU for further action.

21.4 The SERU committee(s) will document, in writing, the basis of the complaints.

21.5 The SERU committee(s) shall review all claims of serious or continuing non-compliance with the SERU requirements. Non-compliance involves conducting research in a manner that disregards or violates the SERUs regulations and/or an approved protocol.

21.6 The SERU committee(s) shall investigate the complaint or concern within thirty (30) working days from the date of the meeting where it was discussed.

21.7 Communication to the PI will be sent within six (6) working days from the date of the SERU review. The PI shall be required to respond to the claim.

21.8 The appropriate SERU committee shall review both the claim and response, upon which the committee may recommend:
   a. Dismissal of the claim as unjustified.
   b. Referral of the matter to another more appropriate process or authority within the respective institutions or other relevant authority for resolution.
   c. Resolution through corrective or educational measures where the violation is minor or inadvertent.
   d. The launch of a formal SERU investigation where the allegation or complaint appears founded and is of a serious nature.

21.9 Should the SERU decide to launch a formal investigation, this shall be referred to the Quality Assurance and Monitoring Department. The PI under investigation shall be given an opportunity to submit written comments and to appear before the investigation committee on at least one occasion before the committee issues a report of its findings. The actions the committee may take with respect to the investigation include but are not limited to:
   a. Dismissal of the complaint as unjustified.
   b. Corrective or educational measures.
   c. Frequent monitoring of research activities.
   d. Recommend frequent reporting by the researcher of his/her research activities.
   e. Recommend restrictions on research practice.
   f. Suspension of approval of one or more of the investigator’s studies.
   g. Termination of approval of one or more of the investigator’s studies.
h. Referral of the matter to other KEMRI committees for possible further review and action by those bodies.

21.10 The SERU may take such measures as necessary to protect the identity of person(s) making allegations and may liaise with KEMRI administration to protect complainants or informants from any retaliatory actions. The complainants or informants shall be reassured of their protection to the extent permitted by law.

21.11 The Head, SERU/Chairperson(s) will notify the PI and the complainant or informant, in writing, the results of the inquiry and reasons for such decision.

21.12 The committee(s) Chairperson/Head SERU shall inform the study sponsor, the Director KEMRI and the Chair and Secretary of the National Bioethics committee (NACOSTI) and where relevant the OHRP of the termination or withdrawal of any ethical approval.
SOP 22: HANDLING OF APPEALS / COMPLAINTS ARISING FROM THE SERU DECISIONS

22.1 Any appeals arising from a SERU Committee decision should be filed by the PI.

22.2 Any PI with a complaint regarding the SERU Committee’s decision on their proposed research study may refer the complaint for review to the Head of SERU in writing, detailing the basis of the complaint.

22.3 The PI may also refer the complaint to the Director KEMRI or may request the SERU Committee Chairperson to do so on his/her behalf.

22.4 The Head SERU/SERU committee Chairperson(s) shall provide the Director KEMRI with all the necessary information about the proposed research study which shall include:
   a. The complaint.
   b. All documents pertaining to the proposed study that was reviewed by SERU.
   c. The relevant section of the minutes detailing SERU’s deliberation on the research proposal.
   d. Further information on the research proposal where necessary.

22.5 The Director KEMRI, in consultation with the relevant committees, shall review the documents provided by the Head SERU/committee Chairperson(s) to determine if further investigation is warranted. The SERU’s decision shall be upheld if it is determined that there is no need for further investigation.

22.6 The Director KEMRI shall inform the SERU and the PI, in writing, of the decision. If it is determined that the appeal deserves further investigation, an Independent Appeals Board shall be constituted to review the petitioned documents.

22.7 In conducting its review, the Appeals Board established by KEMRI shall consider whether the SERU acted in compliance with:
   a. The NACOSTI research guidelines for research clearance and conduct of research.
   b. The SERU Terms of Reference.
   c. The KEMRI Research guidelines.
   d. The SERU Standard Operating Procedures.
   e. The SERU acted in an impartial or biased way.

22.8 The Appeals Board will notify the Director KEMRI, in writing, the outcome of the investigation which may be:
   a. Dismissal of the appeal, in which case the decision the SERU made will be final. The Director KEMRI shall communicate this determination to the SERU and the PI.
   b. Referral back to the SERU for re-consideration with new information obtained by the Appeals Board. If the appeal file is referred back to the SERU for further evaluation, the SERU’s decision on the matter shall be final.
22.9 The board shall communicate to the complainant within five (5) working days of the meeting at which a final decision on the matter was reached.
SOP 23: ENSURING CONFIDENTIALITY OF SERU APPLICATIONS AND PROCEEDINGS

23.1 SERU shall have strict regard to confidentiality of records and of the decisions which are based on consensus of members of SERU.

23.2 SERU committee members and SERU secretariat staff shall be required to sign a confidentiality agreement upon appointment (refer to Appendix H: Confidentiality Agreement Form).

23.3 All SERU documents shall be delivered to the respective SERU committee members’ offices by the SERU Secretariat staff.

23.4 At the end of each SERU meeting, all members shall be required to return their meeting files to the SERU Secretariat and submit their evaluation reports to the Head /Secretary/ Assistant Secretary of SERU. If a SERU member chooses to retain any document for his/her own interest, he/she may do so but shall assume full responsibility for maintaining its confidentiality and for its safe disposal.

23.5 The meeting documents shall be disposed within one (01) year of the respective SERU meeting. The committee members who choose to retain documents must sign a document that indicates that they are retaining the SERU document(s) and they understand that they are responsible for maintaining its confidentiality. Should they destroy the documents in their custody, they must notify SERU in writing.

23.6 All the SERU documents shall be disposed of in a confidential manner such as shredding and/or incinerating.
24.1 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 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 shipment of samples out of the country is anticipated, a separate request and approval will be needed for each shipment.

24.2 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 technology to perform the tests to Kenya.

24.3 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).

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

24.5 A complete application shall include the following items:
   a. A duly signed explanatory cover letter.
   b. One duly completed Request for Shipment Form.
   c. Where applicable, one copy of the initial and current SSC and ERC approval letter for the study.
   d. Where applicable, one copy of the initial and current SERU approval letter for the study.
   e. One copy of the initial and current PPB approval letter for all clinical trials.
   f. One copy of the Approved Consent Documents
   g. The section (s) of the approved protocol which justifies the need for shipment of samples.

24.6 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.

24.7 The SERU Secretariat shall review the application to ensure that:
   a. 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).
   b. The number, type and dimension of tissue blocks to be exported are explicitly defined.
   c. 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.

d. 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.

e. 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.

f. 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.

24.8 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.

24.9 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.

24.10 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.

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

24.12 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.

24.13 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.

24.14 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
25.1 The SERU shall review 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.

25.2 Requirements
   a. A disclosure of the name of the PI for each of the studies from which the samples will be obtained.
   b. A disclosure of the study or studies (give titles and any SERU study identification numbers) from which the samples were derived.
   c. The specific purpose for which the samples are to be used.
   d. Evidence that scientific review of the proposed study has been done to ascertain the merit in conducting the study.
   e. The number and types of samples to be obtained from each study.
   f. An assessment must have been made on 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 will yield meaningful results.
   g. An analysis must have been made on the limitation of the new study presented by the criteria for collecting the samples and the storage conditions and how it will be addressed.
   h. 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.
   i. The arrangements for privacy protections where it is possible to identify the samples.
   j. The identification of the samples must be limited to the extent necessary to achieve the study objectives and a justification should be provided.
   k. A detailed description of the agreements between the investigators on transfer and storage of the biological sample, ownership of data, findings or IPR/patents.
   l. A copy of the previously approved consent document used for the initial collection of the biological specimen.

25.3 For samples collected and archived without notification of future potential uses, the SERU shall make a determination of the scientific merit in using the archived samples and shall provide surrogate consent for their use 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. If the study is likely to produce information relevant to the health or wellbeing of the person who gave the sample, the SERU shall request that appropriate follow-up be done where it is possible to re-contact the study participant.

25.4 The SERU’s discussions on the application shall be recorded in the minutes.
25.5 The SERU shall communicate to the PI, in writing, the decision of SERU on the application within six (6) working days of the meeting at which the decision was reached.
26.1 All documentation and communication of the SERU shall be filed and archived according to the institute’s quality management procedures. The SERU secretariat shall be responsible for accessing and retrieving of the various documents, files, and archives in paper and electronic form.

26.2 All documents received by the SERU shall be retained in the SERU Office for a minimum of three (3) years following completion of a study and then sent to the SERU archives for storage for up to a period of fifteen (15) years or indefinitely as may be applicable. The criteria for length of storage shall be guided by the institute’s quality management procedures.

26.3 The SERU Secretariat shall prepare and archive the following documents:
   b. The published Standard Operating Procedures for the SERU.
   c. The Curriculum Vitae of all SERU committee members.
   d. The SERU committee membership list including their earned degrees, representative capacity, expertise, employment or institutional affiliation of each member.
   e. The training records of SERU members and SERU office staff such as Health Research Ethics, GCP, Monitoring and Evaluation and any other relevant training.
   f. The agenda of the SERU meetings.
   g. The minutes of the SERU meetings.
   h. Copies of all proposed and approved research protocols, scientific evaluations (if any), approved consent documents, annual and status reports, and incident reports.
   i. Copies of all correspondences between investigators and the SERU.
   j. The records of continuing review activities.
   k. The final report of the study.
   l. The record of all site and/or audit visit(s).
   m. All SERU reports.
   n. The electronic database files.
27.1 The proposal for an amendment to a particular SOP or SOPs shall be in writing to the Head, SERU and distributed to all the SERU committee members for their consideration.

27.2 The opinions of the SERU members shall be sought at a convened meeting and any member unable to attend may register his/her views in writing. Only when approved by the SERU members will the proposal be forwarded to the Head SERU, who will then forward it to the Deputy Director Research and Training (DDRT) for final approval. The amendment shall be ratified at the next scheduled SERU meeting and will take effect from the date of approval by the DDRT.

27.3 Any proposed amendment to an SOP or SOPs that is/are not adopted by Head SERU/DDRT shall not be effected.

27.4 When new or revised SOP or SOPs are approved, the Head SERU shall disseminate them to KEMRI staff via e-mail distributions, web postings or educational sessions.
APPENDICES

Appendix A: Sample Annual or Study Status Report (SSC/SERU Form 1)
Appendix B: Requirement for the submission of a NON SSC/NON SERU Research Proposal
Appendix C: Sample Adverse Event Reporting Form
Appendix D: Sample Protocol Deviation or Violation Reporting Form
Appendix E: Sample Curriculum Vitae
Appendix F: Format and Content of an Informed Consent Document
Appendix G: Format and Content of an Informed Consent Document for Genetics Studies
Appendix H: Confidentiality Agreement Form
Appendix I: Format and Content of a Study Closure Report
Appendix K: Evaluation Form for a New Research Proposal
Appendix L: Evaluation Form for a Protocol Amendment
Appendix M: Evaluation Form for Continuing Approval
Appendix N: Evaluation Form for a Safety Report
Appendix O: Guidance on Research Participants’ Rights
Appendix P: Translation Certificate
Appendix Q: KEMRI proposal format
APPENDIX A: SAMPLE ANNUAL OR STUDY STATUS (SSC/SERU FORM 1)

Title of Proposal:

Principal Investigator(s)

SERU No./ SSC No./NON KEMRI No./ NON-SSC No:

1. Project start date: End date:

2. Project period covered: Indicate the project period covered by the current report e.g. 28 February 2016 to 16 January 2016.

3. Research objectives: Briefly describe the purpose of the study.

4. Research progress summary: Briefly describe the progress made during the reporting period, highlighting key findings and achievements during the period. Include the number of new study participants enrolled/recruited into the study, the number of study participants continuing participation and the number of new study participants expected to enroll or leave the study during this period and reasons for their departure. Summarize on-going activities.

5. Amendments: Indicate any amendment applications made to SERU and approved during the reporting period e.g. changes in research site, increase in study sites, sample size, procedure, recruitment plan, investigators, start/end date, modification of informed consent documents, or any other deviation from the original, approved study or protocol violations etc.

6. Adverse events reports: If applicable, report any adverse events – expected or unexpected e.g. related to a drug or a product/procedure being tested that may have occurred during the reporting period, the proportion of the study participants involved, the severity and how the events were handled.

7. Projects outputs: State if there were any publications, abstracts, a product, patent applications, etc. during the reporting period, please list these and provide copies.

8. Constraints: State any constraints experienced during the reporting period, and whether or not they adversely affected project progress. Constraints may include lack of funding, transport, personnel, space etc.

9. Any other relevant information: Include any information that might be relevant to this report but not captured in the items listed e.g. if there has been new literature in the field that may or may not affect the conduct of the study or the risk/benefit status of the study.

10. State whether or not a continuation approval is required for the project.
11. **Plans for the next project year**: State project activities planned for the coming year or continuing into the next year. Indicate if this is the last project year.

12. **Attachment**: Enclose one copy of the current approved study protocol and the current stamped and signed consent documents.
APPENDIX B: REQUIREMENT FOR THE SUBMISSION OF A NON KEMRI/ NON-SSC APPLICATION

1. The application should be addressed to the Head SERU and submitted in the SERU Secretariat Office.
2. The application must be complete before being placed on the next available SERU meeting’s agenda.
3. **Checklist for Completeness**
   a. Five (5) copies of the application and all supporting documents. One of the five copies must have the original inked authorization signatures. The research proposal must be signed by all investigators on the study.
   b. CVs of all investigators on the study duly signed and dated.
   c. Proof of prior scientific review and approval of the proposed research from the PI’s home institution.
4. **Guidance on the Content of an Application**
   a. Research Personnel:
   b. Include a complete list of all key research personnel involved in the conduct of the study, their CVs and clearly define their roles and responsibilities. All key personnel must have undergone training in Health Research Ethics.
   a. Provide a brief abstract of the proposed research.
   c. Study Protocol
      i. Briefly describe the background and significance of the research project.
      ii. Specify the question(s) (aims) of the proposed research and justify the need to conduct the proposed study.
      iii. Describe the study design, population and study procedures.
      iv. If a control or comparison group will be used, a justification should be provided.
      v. Briefly describe the plan to analyze and evaluate the data to answer the research question(s) stated.
      vi. Indicate the number and age range of research participants whose records, data or specimens will be used in the research. If there are different groups of participants, provide the number and ages for each group.
      vii. Define the inclusion criteria for each group of research participants whose records, data or specimens will be used in the research.
      viii. Define the exclusion criteria, if any, for each group of research participants that would exclude the use of these individuals’ records, data or specimens in the research.
      ix. If gender, race or ethnicity is to be used as variables in selecting individuals’ records, data, or specimens for use in the research, the rationale for this should be explained.
      x. Specify the time period in which these records, data or specimens will be collected and/or stored and the timeframe for the entire study.
      xi. Detail the statistical considerations.
      xii. Describe the plan for monitoring the conduct of the study to ensure participants safety, confidentiality and data integrity (include any plans for interim analysis, constitution of a Data Safety and Monitoring Board).
      xiii. Clearly describe the data management and analysis plan.
xiv. Describe any study limitations and the expected results.

xv. Provide an itemized budget needed to conduct the research and a budget justification.

xvi. Provide copies of the research data collection forms to be used or a complete list of data variables that will be collected.

d. **Ethical Considerations**

i. If the research involves any risk to research participants and their privacy, a clear description of the risks should be provided.

ii. If a proposed research could not practically be carried out without the waiver of consent, this must be clearly explained.

iii. If a proposed research could not practically be carried out without access to protected health information, this must be clearly explained.

iv. Identify all the sources of the data, records or specimens to be used in the proposed research (Attach Data Collection Forms, Case Report Forms to be used in the investigation).

v. Indicate the measures in place to maintain the confidentiality of the research data and protect the privacy of research participants.

vi. Provide a description of where research data/specimens being collected will be stored; specify the duration of storage and the measures to be taken to ensure security of data/specimens; identify the custodian and who will have access to the data/specimens.

vii. Describe the plan for controlling access to the stored research data and/or specimens.

viii. If persons not listed as PI or research team member will receive or view research data with identifiers, a justification for this must be provided.

ix. All members of the research team with access to confidential records, data or specimens collected for the research must sign the appropriate institutional agreement(s).

x. Describe the potential benefits of the research to community and/or society.

xi. If information is being collected from others e.g., health care providers, family members of the individuals whose records, data or specimens are being used, an explanation of the potential risks to these individuals from the results of the research must be provided.

xii. Consent issues: Describe how assent/consent will be obtained; describe the plans for assuring ongoing consent from research participants or their legally authorized representatives; describe the procedures to be followed should a research participant wish to withdraw their consent either during or after the study.
APPENDIX C: SAMPLE ADVERSE EVENT REPORTING FORM

Title of Proposal:

Principal Investigator(s)

SSC/SERU/NON-SSC/NON KEMRI No.
1. PI’s mailing address:
2. Date of Report:
3. Type of Report: Initial or Follow-up
4. Study participant information: Identification number, age, height, weight, etc.
5. Adverse event start date: Adverse event stop date: or Ongoing
6. State the location of the event, if applicable:
7. Describe the adverse event: Describe the signs, symptoms, severity, time course, relevant medical history and laboratory data. Include results of confirmatory procedures, if any. Indicate any medication required to treat the event and the outcome.
8. Give a presumptive diagnosis
9. Describe the investigational drug, medical treatment or procedure or device causing the event.
10. Describe the circumstances of the event, where applicable: Death (whether an autopsy was done), congenital abnormality, indicate whether it is life-threatening, if prolonged hospitalization is required, if persistent or significant disability occurred, if the study participant requires medical or surgical intervention to prevent other outcomes.
11. Describe the action taken:
13. State the relationship to the drug/participation in a project: not-related, possibly, probably, definitely, unlikely related to drug/participation and explain why.
14. State if the adverse event is described in the current approved informed consent/assent document.
15. State if the event requires a change or changes in the consent/assent documents and to the study procedures.
16. State whether or not the enrolled study participants will be advised of the event. If yes, explain how this new information will be conveyed. If not, explain why.
17. Indicate whether the study sponsor and/or the DSMB have been notified.

_________________________ ____________________
Typed name Signature of the PI Date:
APPENDIX D: SAMPLE PROTOCOL DEVIATION OR VIOLATION FORM

Title of Proposal:
Principal Investigator(s)
SSC/SERU/NON-SSC/NON KEMRI No.:
1. Date of Deviation/Violation:

2. Study Participant number (where applicable):

3. Name of treating physician (where applicable):

4. Provide a description of the deviation/violation: State whether the study participants were adversely affected by the deviation/violation; whether the deviation/violation placed the study participants at greater risk and whether the study participants were informed of the deviation/violation, where applicable.

5. Provide an explanation as to why the deviation/violation occurred.

6. Describe the measures taken to address the deviation/violation.

7. Describe the measures taken to preclude future recurrence of the deviation/violation.

8. Indicate whether the study sponsor has been notified.

_________________________________________________
Typed name Signature of the PI Date:
APPENDIX E: SAMPLE CURRICULUM VITAE

A Curriculum Vitae (CV) must demonstrate that an investigator is qualified by education, training and experience to conduct the proposed research. A standard template for an investigator CV is set out below and is issued as a guide. The SERU requires that experience relevant to the specific research study is fully summarised, but the overall document should be kept concise (no more than five (5) pages) and should not include a lengthy list of publications.

Name:

Address: (Full work address)

Telephone number:

Email address:

Qualifications:

Professional affiliation/registration (if applicable): Name of body, registration number and date of registration.

Present appointment: Job title, department, and organisation.

Previous and other appointments: Include previous appointments in the last five (5) years and other relevant appointments.

Research experience: Summary of research experience, including the extent of personal involvement. Refer to any specific clinical or research experience relevant to the current application.

Research training: Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, Monitoring and Evaluation, Informed Consent Process or other training appropriate to non-clinical research. Give the date(s) of the training.

Relevant publications: Give at least five relevant references

Referees:

Signature:

Date:

N.B. Maximum number of pages per cv: 5 pages
APPENDIX F: FORMAT AND CONTENT OF AN INFORMED CONSENT DOCUMENT

The level of language and syntax used should be appropriate to the age, comprehension and reading level of the study population. The use of legalistic phrases, scientific and medical terminologies should be avoided. Volumes, weights as well as scientific measurements should be expressed in meaningful scales (e.g. blood draws in numbers of teaspoonfuls, tablespoonfuls or proportion of a National Blood Services donation).

All consent documents must have a version number, date and stamped by the SERU Secretariat.

PROPOSED FORMAT OF A CONSENT FORM

Title of the Research Study:

Investigator(s) – Local and International Collaborators: Provide the name and institutional affiliation of all investigators on the study. List PI first followed by co-investigators.

Study location: Indicate where the study will be conducted.

Purpose of the Research: Briefly describe the purpose of the study.

Description of the Research:
The study you are about to participate in is (briefly describe the study). Should you agree to participate in the study, you will be asked to (summarize study procedures).

a. Provide a brief description of the proposed research as it will be experienced by the research participants. Interventions or procedures that are part of standard care and those that are research must be distinguished.

b. If specific testing (e.g. HIV testing, HLA typing) will be done as part of the research, this must be explained.

c. If the study participant is receiving any therapy prior to enrollment in the study and this therapy will or may be altered or discontinued as a result of participation in the study, this must be explained.

d. If randomization or sequential assignment is planned, this must be explained.

e. If blood will be drawn, the total volume (teaspoons and millilitre equivalents) must be indicated and a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection should be provided. If other specimens (e.g. urine, stool, saliva etc.) will be collected, the study participants must be informed.

f. The frequency and duration of specific testing, as well as the duration of the entire study should be specified.

g. The study participants should be informed that any changes made to the study or should new information become available, he/she shall be so informed.
h. If future use of the research data beyond the current study is anticipated, this should be clearly explained. If the research data/samples are to be destroyed after the study is complete, study participants must be informed of the plan.

i. If any tests will be done at other locations, the study participants must be informed of the location where the testing will be done and the purpose for the tests. This information must also be reflected in the body of the research protocol.

j. If a questionnaire will be administered or interview conducted, a description of the questionnaire/interview, the length of time it will take to complete it must be provided; the participants must also be informed that they may choose not to answer any questions or withdraw at any time.

k. If data will be abstracted from medical records or from other confidential sources, this must be so described.

l. The study participants must be informed if a study involves videotaping, taking photographs or audio recordings.

m. If products of commercial importance may be developed from blood samples, DNA, RNA extracted, so state and describe the plans for benefit sharing.

Potential Harm, Injuries, Discomforts or Inconvenience, Risks:

a. If there is no known or known harm/risk to the study participants, this should be clearly stated.

b. If there is known or anticipated risk, this must be clearly enumerated.

Potential Benefits:

a. If study participants will not benefit or might benefit directly from participation in the study, this should be stated and the potential benefits should be described.

b. If the community in general or patients with a similar condition stands to benefit from the results of the study, this should also be explained.

Alternative Procedures or Treatments:

a. If there is no treatment alternative, the alternative to participation in the study is non-treatment and this should be explained.

b. If there is/are a treatment alternative(s), the alternative(s) should be identified and described.

c. If the research is not about a treatment, this section may be omitted.

Confidentiality:

a. No information that reveals the identity of any study participant should be released or published without consent.

b. If access is required by a sponsor, SERU or other health regulatory authorities for the purpose of monitoring the study, this must be explicitly stated.

c. The plan for maintaining confidentiality of research records and materials must be clearly explained.

Reimbursement:

a. Study participants or their parents/guardians can be reimbursed for loss of wages, transportation expenses and for their time. Under no circumstances should payment be offered for harm or discomfort.
a. It should be clearly stated that if the study participant withdraws from the research, that there will be appropriate pro-rated reimbursement, where applicable.

b. A token of appreciation may be presented after completion of the study, but this should not be mentioned in the research consent document but must have been indicated in the body of the study protocol.

c. Include specific information whenever study participants will receive an inducement.

**Participation:**
a. If there are parts of the research study in which a study participant may choose not to participate, this should be clearly explained.

b. Parents/guardians of study participants should be made aware that assent may be required from their child.

c. All study participants must be given a copy of the signed and dated consent form to keep.

d. The plan for referrals for further medical care or treatment should be explained, where applicable and clarify who will be responsible for the cost of such treatment.

**Sponsorship:**
In situations where a study may be terminated at the discretion of the investigator or the study sponsor even if the study participants are benefiting, there should be provision for discussing the next course of action with the study participants and/or procedures for orderly termination.

**Contact:**
a. For any questions or concerns about a study or in the event of a study-related injury, the contact person is the principal investigator and/or the principal investigator’s representative who should provide his/her 24-hour contact telephone number. The physical address must also be provided.

b. For any questions pertaining to your rights as a research participant, the contact person is: The Head, SERU, P. O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717-719477; Email address: seru@kemri.org/serukemri@gmail.com

All data collected from you will be coded in order to protect your identity, if applicable. Only the research study staff will have access to the information. At the end of the study, there will be no way to link your name with your data (where applicable). Any additional information about the study will be provided to you including the final study results.

You are free to withdraw or refuse to answer any questions at any time without any consequences. Should you agree to participate in the study, please sign your name below, indicating that you have read and understood the nature of the study, your responsibilities as a study participant, the inconveniences associated with voluntary participation in the study and that all your questions and concerns concerning the study have been answered satisfactorily.

You will receive a copy of this signed consent form to take away with you.

_________________________________ ________________________
Signature of Study Participant and Date Thumbprint of Study

Participant and Date
Signature of Person Obtaining Consent and Date

______________________________
Signature of Witness and Date
APPENDIX G: FORMAT AND CONTENT OF INFORMED CONSENT FOR GENETIC STUDIES

Title of the Research Study:

Investigator(s) – Local and international collaborators: Provide the name and institutional affiliation of all investigators on the study.

Study location: Indicate where the study will be conducted.

Purpose of the Research: Briefly describe the purpose of the genetic study in a language that should be understandable to the study population.

Procedures: Briefly describe how sample collection will be done, who will handle the sample(s), the location and duration of storage of the samples and indicate whether the study participant may be contacted in the future about the sample and/or study results.

Risks and Benefits: Briefly describe the common risks associated with sample collection and describe any potential risk if the genetic information is disclosed, either intentionally or inadvertently.

Confidentiality: Briefly describe the mechanisms that will be used to protect unauthorized access to the genetic material or information derived from it and the plans to destroy the sample in the future. Indicate whether the sample may be withdrawn at a later date if a study participant refrains from participating in the genetic aspect of a study.

Coding of samples: The type of coding of a sample must be specified because a sample that is anonymized cannot be withdrawn in the future.

Commercialization: The study participant(s) must be informed if there could be a potential for commercialization benefit from the results obtained using their sample. If that be the case, it must be clearly stated how the study participant, family or community stand to benefit.

All other elements of informed consent apply
(Refer to Appendix F: Format and Content of an Informed Consent Document)
Confidentiality Agreement  
KEMRI SERU MEMBER

I, ______________________________________________________________, agree to maintain full confidentiality in regards to any and all documentation received from researchers, Scientific and Ethics Review Unit (SERU) Committee members “the Committee” and other entities in matters related to SERU function.

Furthermore, I agree:
1. To adhere to the SERU Office Management Procedures.
2. To ensure that all SERU related documents are in a safe, secure location as long as they are in my possession.
3. To not make copies of any documents received at the SERU Office unless specifically requested to do so by the principal investigator or his/her representative, the Committee and KEMRI Management.
4. To not to discuss, disclose, or reproduce any confidential information except when I carry out my functions as an SERU Member.
5. To hold in strictest confidence the identification of any individual that may be reprimanded by the Committee.
6. To delete all electronic files containing SERU-related documents from my computer hard drive and any backup devices when I leave the SERU Office.

I am aware that I can be held legally liable for any breach of this confidentiality agreement and for any harm incurred by individuals as a result of the violation.

Name: (printed) ____________________________________________________________

Signature:_______________________________________________________________

Date:_______________________________________________________________

Witnessed by the SERU Committee Chairperson:

Name: (printed) ____________________________________________________________

Signature:_______________________________________________________________

Date:____________________
APPENDIX I: FORMAT AND CONTENT OF A CLOSURE REPORT

Title of Proposal:

Principal Investigator(s):

SSC/NON-SSC/SERU/NON KEMRI No.:

1. Project Start Date: End Date:

2. Total number of study participants enrolled:

3. Provide a summary of research activities including follow-up procedures:

4. Describe the study results:

5. Attach any publication arising from study (attach copies of the manuscript(s))

6. Describe the plan to refer back to medical records to verify research data (if applicable)

7. Detail the plan of destruction of each study participant’s identifiers and provide an assurance that the destruction has occurred.

8. Detail the plan for future use of data from the study (if applicable)

9. Detail the plans of destruction of surplus investigational agents and provide an assurance that the destruction has occurred (if applicable)

10. Detail the plan for the destruction, storage, or future use of biological specimens obtained as part of this study (include number of samples being destroyed or stored)

11. Send annual report of the progress if any activities have been done.

______________________________________________
Signature of Principal Investigator(s) Date
APPENDIX K: EVALUATION FORM FOR A NEW RESEARCH PROPOSAL

Title of proposal: Check lists: PIs to include a check list with their application
Principal Investigator(s) SSC/NON-SSC/SERU/NON KEMRI No.:

1. Are the roles of all investigators on the study defined?

2. Are there local investigators including Co-PI?

3. Is there a scientific basis for initiating the study?

4. Is the research relevant to the health needs of the community under study?

5. What is the social value of the proposed research?

6. Are the objectives clear & achievable?
   a. Suitability of study design
   b. Appropriateness of Study Procedures
   c. Plans for data collection, storage and analysis
   d. Ethical considerations
   e. Statistical considerations

7. Study Population
   a. Fair selection & recruitment procedures
   b. Incentives to participate and compensation. Are these elements appropriate and non-coercive?
   c. Does the research include special or vulnerable populations? If yes, is it possible to exclude them and still answer the same study questions? Are adequate measures in place to ensure that the populations are well protected?
   d. Adequacy of Consent Document and translations
   e. Process for assuring that consent/assent is voluntary
   f. Provision for privacy and confidentiality protection
   g. Adequacy of study instrument(s) and their translations into the relevant local language
   h. Is there justice?

8. For animal-based studies, is the study approved by the KEMRI ACUC? If yes, give date of approval. If no, do not review.

9. Are the intellectual property issues addressed?

10. Are the biosafety issues addressed?

11. Level of risk/harm the study presents:
    a. Minimal risk/harm
    b. More than minimal risk/harm
    c. High risk
12. Identify and assess the risks and anticipated benefits.

13. Is there provision for capacity building and/or technology transfer?

14. Comments, suggestions or recommendations:

15. Comments during meeting:
APPENDIX L: EVALUATION FORM FOR A PROTOCOL AMENDMENT

Name and Signature of Reviewer:

Title of proposal:

Principal Investigator(s)

SSC/NON-SSC/SERU/NON KEMRI No.:
1. What is the amendment?

2. What is the justification/rationale for the suggested amendment? Is it warranted?

3. Does the amendment involve protocol revisions? Is the revised protocol provided for review?

4. Does the amendment involve revisions to the consent documents? Are the revised consent documents provided for review?

5. Will the enrolled study participants be informed of the change(s)?

6. Does the amendment involve revisions to questionnaires and/or survey forms, interview questions, and recruitment materials? Are the revised materials provided for review?

7. Does the amendment alter the study eligibility criteria?

8. Does the amendment affect drug preparation or administration or treatment plans? (if applicable) How?

9. Does the amendment involve the removal or addition of an investigator? Is a letter from investigator who has relinquished his/her position and responsibilities provided? Is the CV of the new investigator (if not affiliated with KEMRI) provided and is his/her role defined?

10. Is the amendment being submitted as a result of an adverse event? Is the safety report included for review?

11. Is the amendment being submitted as a result of DSMB/DMC advice? Is the report included for review?

12. Does the amendment alter the risk/benefit status of the study?

13. Comments, suggestions or recommendations:

14. Comments during meeting:
APPENDIX M: EVALUATION FORM FOR CONTINUING APPROVAL

Name and Signature of Reviewer:

Title of proposal:

Principal Investigator(s):

SERU/ SSC/ NON KEMRI/ NON-SSC/ No.:

1. Is there evidence of compliance with provisions of the approved research study? If yes, so state. If not, explain why.

2. Does the risk/benefit status of the research remain unaltered?

3. Does the consent document contain information that is up-to-date? Version number and date?

4. Achievements made in the reporting period:
   a. Has significant progress been made? If yes, so state. If no, explain why
   b. If research is completed, what is the outcome? Has the initial hypothesis or research question been substantiated by the findings?

5. Plans for the next twelve (12) months:
   a. Are the proposed plans for the next twelve (12) months scientifically sound?
   b. Are the proposed plans justified and achievable?
   c. Is the proposed budget for the next twelve (12) months appropriate?

6. Suggestions, comments or recommendations regarding the annual report or the proposed plan for the next study period:

7. Comments during meeting:
APPENDIX N: EVALUATION FORM FOR A SAFETY REPORT

Name and Signature of Reviewer:

Title of proposal:

Principal Investigator(s)

SSC/NON-SSC/SERU/NON SERU No.:
1. What is the event?

2. How many study participants experienced the event?

3. What is the PI’s determination of the event?
   a. Serious or not serious?
   b. Expected or unexpected?

4. Does the event place the study participant or others at greater risk or harm than is previously known?

5. What is the PI’s determination of the events relationship with the participation in the study?

6. Comments, suggestions or recommendations:

7. Comments during meeting:
APPENDIX O: GUIDANCE ON RESEARCH PARTICIPANTS’ RIGHTS

Each person who is asked to participate in a research study has a right to:

1. Be informed of the purpose of the research study.
2. Be informed of what will happen to them or their child during the course of a particular research study.
3. Be informed of any procedures, drugs or devices that are different from what would be used in standard clinical practice.
4. Be informed of the risks, side effects or discomforts of any procedure that will happen during the course of the research study.
5. Be told if they or their child can expect any benefit from participating, and if so, what the benefit might be.
6. Be told of the other choices available to them or their child and how the choice may be better or worse than what is currently being offered by the study.
7. Be allowed to ask any questions concerning the study both prior to agreeing to be involved in the research study and during the course of the research study.
8. Be told what sort of treatment is available should any complications arise during their participation in a study (clinical trial).
9. Be free from duress when considering whether the individual or their child wishes to participate in a research study.
10. Be free to refuse to participate at all in a research study or change their mind about their participation or their child’s participation after the study has begun and that any decision made will not affect the care the individual or their child would receive if they were not in the research study.
11. Be given a copy of the signed and dated consent form to keep.
TRANSLATION COMPLIANCE FORM

---Please fill in all sections of this form---

PI(s): ______________________

Protocol Title: ________________

Translations Requested by: ________________ Date Requested: ________________

Translation Reference N° (if applicable): ______________________

**Document Details:**

<table>
<thead>
<tr>
<th>Document Details</th>
<th>Unique Document ID*</th>
<th>Date of original Document</th>
<th>Language of Original Document</th>
<th>Translated Language Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Unique document identification: for example version N°, date, etc.

**Translation Details**

Name of Translator: ______________________

Function of Translator: ______________________

Address of Translator: ______________________

Signature of Translator: ______________________

Date of Translation(s): ______________________

    dd/mm/yyyy
Review Details

This translation was/these translations were reviewed for accuracy, consistency, and clarity with the original document(s) by:

Name of Reviewer: ______________________

Function of Reviewer: ____________________

Address of Reviewer: ________________

Comments on Translation(s):
(Please document below any comments you may have on the translations(s) or if you feel further work on or re-work of the document(s) is necessary)

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

Signature of reviewer: ______________________

Date of review: ______________________

dd/mm/yyyy
APPENDIX Q: KEMRI PROPOSAL FORMAT

The proposal should have the following elements:

1. Adapt the continuous line numbering
2. Document control system: Provide the version number and date.
3. **TITLE OF THE PROJECT:**
   a. This should be concise and not longer than 30 words.
4. **INVESTIGATORS AND INSTITUTIONAL AFFILIATIONS:** Non-KEMRI investigators should attach their *curriculum vitae* (Maximum of two pages) or a biosketch.
5. **LAY SUMMARY:** Maximum a page.
6. **ABSTRACT:** It should provide a concise summary of the background, - , objective, methods, significance
7. **INTRODUCTION AND /LITERATURE REVIEW:**
   a. This should be a historical and/or scientific background to the project proposal with literature citations. The literature cited should be listed at the end of the proposal document.(3-5 pages exemption for Clinical Trial Applications)
   b. For student research proposals, the introduction and literature review sections should be separated.
8. **JUSTIFICATION FOR THE STUDY**
   This section should –emphasize how the results will provide new knowledge in the particular field, and why it will be important for national or international development.
9. **STATE THE NULL HYPOTHESIS (if applicable) OR RESEARCH QUESTIONS.**
10. (a) **GENERAL OBJECTIVES.**
   The main aim should be given clearly.
   (b) **SPECIFIC OBJECTIVES.**
   This section must clearly state the objective(s) of the project. These must be achievable objectives and not statements of the methods to be carried out. The objectives should be written in short concise sentences [*Preferably up to five specific objectives should be given*]
8. **DESIGN AND METHODOLOGY**
   a. Study design could include case-control, descriptive, surveillance, cross-sectional, prospective, retrospective, hospital/lab based, CT, etc) Study site (geographical location and/or site description)
   b. Study populations
   i. Eligibility criteria
   c. Inclusion and exclusion Criteria should be justified
   d. Rationale for animal use and justification for animal species chosen.
   e. Sampling
   i. Sample size determination if applicable.
   f. Sampling procedure.
   i. (provision for convenient sampling)
   g. Data Collection
   i. Lab procedures.
   ii. The structure of this section will be determined by the specific nature of the study. If it is a clinical study, it should specify such things as study site, patient selection, inclusion and exclusion criteria, summary of the procedures to be used, etc. If it is a
laboratory and/or field study, it should specify the study site, materials, procedures to be used preferably in bullet form, etc. Where appropriate, calculation of the subject/patient population should be shown. The instruments to be used in surveys, clinical studies, questionnaires, should be appropriately mentioned in the text and copies of such instruments should be attached to the proposal document in the form of Appendices. Similarly, the INFORMED CONSENT FORMS AND EXPLANATIONS should be attached as Appendices.

iii. Nested studies (abstract of parent proposal/ provide sufficient information on the parent study and how the studies are linked)

iv. If PI of parent study is in another institution, letter of authorization from the PI/copy of letter of approval/)

9. ETHICAL CONSIDERATIONS

10. INTELLECTUAL PROPERTY CONSIDERATIONS

   i. KEMRI IP policy/Chapter XX and appendices

   ii. Proposal level: PI declares if there is potential for IP

   iii. MTA – Shipment of biological samples/Data sharing

   iv. Involvement of third party – aid in commercialization

   v. Measures in place to protect data – collection to dissemination

11. DATA, MANAGEMENT, STORAGE, DISSEMINATION

   a. Data Storage.

      i. Provision for database management incorporating how data will be stored before and after analysis.

      ii. Description of devices to be used for storage, i.e. type of computer software to be used in data entry, checking and management.

   b. Data Management

      i. Data Analysis - The statistical software and tests to be applied in the analysis to meet the requirements of each of the specific objectives and hypotheses to be tested.

      ii. This section should concisely describe how the data obtained will be processed, calculated or computed. If a computerized method is to be used, it should specify which software(s) will be used and HOW it will be used. Such statements like "The results will be entered in a computer" without any further explanation will not be accepted. Where results will be processed in the form of tables, a short form of such tables should be given with the headings.

         a. Collaborative research – ownership of data, data access, sharing of data

         b. Commissioned studies – requirements must be spelt out and a Memorandum of Understanding executed in advance

         c. Declaration of any possible Conflict of Interest on the proposal developed especially if expected results of data may benefit the researcher financially or other

12. ANTICIPATED TIME FRAME/DURATION OF THE PROJECT:

   Gantt chart: Give a brief summary of the timing of events in the implementation of the project, using any of the following or any others;

   a. Pilot study (where applicable)

   b. Definitive study

   c. Data analysis

   d. Report preparation

   e. The total period planned for the project should be stated in months or years, followed by
a breakdown of the stages of implementation.

13. **EXPECTED APPLICATION OF THE RESULTS.**
   a. This section should summarize briefly the importance of the expected results and their potential use or application.

14. **REFERENCES within text**
   i. **Journals**
      a. Single author should be the surname, year of publication Smith, 2013:
      b. Two authors: respective surnames, year of publication : Smith and Craig, 2006
      c. For more than two authors: One surname, *et al.*, year of publication : Kithinji *et al.*, 2013 (*et al.*, should be italicized)
      d. Multiple references on a single point : Kithinji *et al.*, 2013; Smith and Craig, 2006 etc.)

   **Examples:**
   ii. **Books**
      b. **Books where the author and publisher are the same**
   iii. **Website**
      a. Full address and the date of access
         **Example:**
         **Library database**
   iv. **Bibliography**
      In the References page, use the following citation system:
The literature citations should be provided in full detail, preferably using the numbering style, but in any case, each reference cited in the project proposal must be listed giving: the names of the authors, the full title of the publication, the year of publication, the volume if it is a serial or authors and publishers if it is a book, the beginning and end pages of the article. 75% of the references should not be more than 5 years old.

15. **BUDGET**
The budget section should be written in three parts:

a. **Budget Summary** which should list the major components of the budget, e.g. Travel, Staff emoluments, Equipment, etc.
   i. The item costs should be given in convertible currency e.g. USD, UK POUNDS etc, but at the end, the total equivalent in Kenyan Shillings at the time of writing the project, should also be given.
   ii. Personnel, salaries and benefits disbursement
   iii. Patient costs, travel, food and/or supplies
   iv. Major equipment itemized; minor aggregated
   v. Supplies
   vi. Travel and accommodation:
      a. Local or field travel
      b. International/Local conferences
   vii. Transportation, vehicle repairs, insurance, etc.
   viii. Operating expenses, postage, printing, etc.
   ix. Animals: acquisition, food, cages, etc.
   x. Consultancy fees
   xi. Contingency funds (15% including inflation)
   xii. Institutional administrative overheads: 15%

b. **Budget Justification**
   Justification for each line in (i) above should be given.

16. **APPENDICES**

a. State the role of each participating investigator.

b. Attach the relevant documents:
   i. Curriculum vitae of each non- KEMRI investigator – limit to 2 pages
   ii. Case record and data collection forms
   iii. Informed consent advice and forms