Monitoring Ethical Compliance and Integrity in Research: Self-Assessment tool

TOM MBOYA UNIVERSITY- SERC
March 2026

Purpose: This form is a tool for researchers to use as a self-assessment of their SERC approved study to ensure that the regulatory and institutional requirements for maintaining ethical compliance are met.
Principal investigators from all campuses are required to complete this mandatory self-assessment together with the annual progress report after receiving SERC approval.

The self-assessment is an institutional AKU requirement in order to achieve 100% monitoring of ethical compliance.

If you should have any questions or concerns regarding self-assessment, contact the respective Ethics Review Committees Offices.

Principal Investigator:	
Title of Grant/Research Study:	
Co-Investigator(s):	
Research Team:	
Institution:	
Department:	
Sponsors/funding. (Select)	**URC/Seed Money** □ **External Funded** *Local or* □ *Overseas* □ **Self-Funded** □
Date of SERC Approval:	
SERC number:	
Date of start of the project:	
If the project has not commenced, or commencement delayed, advise when the project is expected to commence or whether the project is to be withdrawn or what is the reason for delay in starting the project work?	
Date of Completion (If applicable)	

Self- Assessment
Monitoring Ethical Compliance (MEC)

Designated person for self –Assessment (If not PI)					
Date of self-assessment/monitoring					
					Date/Comments
1.	SERC approval for full review ( ) exemption ( ).	Yes	No		
2.	Any concerns/reservations from SERC addressed, in the process between submission and approval.	Yes	No	NA	
3.	Approval/exemption from the national accreditation body (NBC/NACOSTI, IMRI) has been received.	Yes	No	NA	
4.	Progress report submitted to the SERC on time. (After One Year of the approval) *(If applicable)*	Yes	No	NA	
5.	SERC renewal obtained. *(If applicable)*	Yes	No	NA	
6.	SERC approval lapsed and research activities continued.	Yes	No	NA	If Yes, give reasons
Comments:					
Project Activities					**Date/Comments**
7.	The project is running in accordance, with the protocol approved by SERC	Yes	No	NA	
8.	Was there any protocol deviation?	Yes	No	NA	
9.	If yes for the Q 8- Action taken to avoid recurrence.	Yes	No	NA	
10.	If changes or deviation: SERC was informed for approval.	Yes	No	NA	
11.	Was SERC approval taken?	Yes	No	NA	
12.	Delegation of Authority (Responsibility) Log maintained *	Yes	No	NA	
13.	Persons responsible to enroll study participants are qualified and have received the necessary training.	Yes	No	NA	
14.	Persons responsible have full knowledge of the study protocol and risks associated with participation.	Yes	No	NA	
15.	Recruitment of participants has been duly supervised and was noted to be satisfactory with full disclosure.	Yes	No	NA	

Self- Assessment
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16.	Well understood informed consent has been taken from every participant/surrogate according to the process described in the protocol	Yes	No	NA	
17.	Participants who want to withdraw from the study are facilitated to do so and their data has been removed	Yes	No	NA	
18.	Consent forms are appropriately signed by the participants.	Yes	No	NA	
19.	PI or delegated person has conducted a ***periodical*** review of all consent forms to ensure ethical compliance.	Yes	No	NA	Daily/Weekly/Fortnightly/Monthly
20.	Consent forms are stored securely and are available for audit.	Yes	No	NA	
21.	In the case of illiterate subjects, thumb impression was obtained in front of an impartial witness.	Yes	No	NA	
22.	For the vulnerable participants consent from a surrogate in the presence of an impartial witness has been obtained.	Yes	No	NA	
23.	In the case of children between 7 to <18 years of age: Parental consent and the child assent have been obtained.	Yes	No	NA	
24.	Healthcare waste produced in this research project is handled according to the established guidelines	Yes	No	NA	
25.	All necessary steps have always been taken to ensure the safety of the research team; especially during COVID pandemic.	Yes	No	NA	
Research Participants Safety.					**Date/Comments**
26.	Risks to participants in the research have been identified and measures are taken to minimize them.	Yes	No	NA	
27.	Insurance/financial resource to cover adverse events/ harm is available and current during life of study.	Yes	No	NA	
28.	Compensation or medical treatment coverage is provided in accordance with the SERC approved consent form.	Yes	No	NA	
29.	Reporting of adverse event (minor) was noted and SERC was informed. Was same reported within stipulated period?	Yes	No	NA	
30.	Reporting of the serious adverse event observed and immediately notified (within 24 hours) to respective SERC.	Yes	No	NA	
Comments:					
Project related documents/Master folder					**Date/Comments**
31.	Study Master File (Investigator site file? ISF) containing signed protocol and amendments, regulatory approvals, delegation log, training logs, Study Specific SOPs, contracts	Yes	No	NA	

	and agreements, consent forms, data collection tools and complete record of correspondence with SERC. **				
32.	Documentation is up to date, accessible, clearly ordered and comprehensible for external monitors/sponsors review.	Yes	No	NA	
Comments:					
Integrity and safety of data					**Date/Comments**
33.	Physical security of data is adequately maintained. All consent forms, questionnaires and study-related documents are stored in a secure place. Only relevant persons can access the data.	Yes	No	NA	
34.	Electronic data is secured, and password protected, and only relevant persons have access to electronic data.	Yes	No	NA	
35.	Ensured confidentiality and security of the data.	Yes	No	NA	
36.	The project is compliant with MTA and DTA.				
37.	Disposal of residual biological material is in compliance with institutional policies.				
Comments:					

Principal Investigator_____

Signature: _____

Date: _____

NA= Not Applicable

* Delegation of Authority from PI- If applicable e.g. Clinical Trials, Clinical/Hospital Studies, Intervention Studies.

**Master Folder includes,

Self- Assessment
Monitoring Ethical Compliance (MEC)

- Protocol (All versions)
- SERC Correspondence including Letter of approval/Extension, Annual Report (if applicable).
- Approvals from National Accreditation Bodies.
- All CRFs
- Consent/Assent Forms.
- Questionnaire/s or any other data collection tool.
- Contract Agreements
- Training Logs and Certificate