



KENYATTA UNIVERSITY
CENTRE FOR RESEARCH ETHICS AND SAFETY
Kenyatta University Ethics Review Committee

PROTOCOL PRE SUBMISSION CHECKLIST

To be completed by applicants prior to submission to the Ethics Review Committee

Applicant Name:

Protocol Title:
.....
.....

A) Scientific Design and Conduct of the Study

	YES	NO	N/A	COMMENTS
a) Objectives clearly stated	☐	☐	☐	
b) Scientific rationale provided	☐	☐	☐	
c) Study design appropriate	☐	☐	☐	
d) Methods clearly described	☐	☐	☐	
e) Feasibility addressed	☐	☐	☐	
f) Statistical plan and sample size justified	☐	☐	☐	
g) Risk benefit assessment included	☐	☐	☐	
h) Scientific validity ensured	☐	☐	☐	

B) Recruitment of Participants

	YES	NO	N/A	COMMENTS
a) Eligibility criteria defined	☐	☐	☐	
b) Recruitment methods fair and non coercive	☐	☐	☐	
c) Equity and inclusion considered	☐	☐	☐	
d) Recruitment materials clear and accurate	☐	☐	☐	
e) Compensation appropriate	☐	☐	☐	

C) Care and protection of Participants

	YES	NO	N/A	COMMENTS
a) All foreseeable risks identified	☐	☐	☐	
b) Risk minimization strategies described	☐	☐	☐	
c) Safety monitoring procedures included	☐	☐	☐	
d) Referral/support procedures in place	☐	☐	☐	
e) Participant rights to withdraw emphasized	☐	☐	☐	

D) Protection of participants confidentiality

	YES	NO	N/A	COMMENTS
a) Data collection limited to necessary information	☐	☐	☐	
b) Secure data storage outlined	☐	☐	☐	
c) Data anonymization described	☐	☐	☐	
d) Data sharing plans protect privacy	☐	☐	☐	



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- e) Procedures for confidentiality breaches included ☐ ☐ ☐
- f) Data retention period included ☐ ☐ ☐

E) Informed consent process

	YES	NO	N/A	COMMENTS
a) Consent forms clear and understandable	☐	☐	☐	
b) Purpose and study procedures explained	☐	☐	☐	
c) Risks,benefits,confidentiality, compensation,withdrawal included	☐	☐	☐	
d) Consent process ensures voluntariness	☐	☐	☐	
e) Capacity assessment for decision making	☐	☐	☐	
f) Ongoing consent process described	☐	☐	☐	
g) Assent form attached if participants are under 18 years	☐	☐	☐	

F) Community considerations

	YES	NO	N/A	COMMENTS
a) Community engagement planned	☐	☐	☐	
b) Cultural sensitivity addressed	☐	☐	☐	
c) Community benefits considered	☐	☐	☐	
d) Potential social harms minimized	☐	☐	☐	
e) Plans for dissemination to participants /community described	☐	☐	☐	

Final Checks

	YES	NO	N/A	COMMENTS
1. All attachments included;				
Protocol	☐	☐	☐	
Consent forms	☐	☐	☐	
Assent forms for under 18 years participants	☐	☐	☐	
Recruitment materials	☐	☐	☐	
Questionnaires	☐	☐	☐	
2. Regulatory approvals and safety monitoring plans documented	☐	☐	☐	
3. Protocol reviewed for clarity and completeness	☐	☐	☐	

Declaration:

I confirm that I have reviewed this checklist and completed all items to the best of my knowledge.

I understand that an incomplete or inaccurate information may result in delays in ethics review.

Applicant Signature:.....

Date:.....