NATIONAL AIDS CONTROL ORGANISATION

Strategic Information Management Unit
(Research & Evaluation)

FORMAT FOR SUBMISSION OF RESEARCH PROPOSAL FOR ETHICAL CLEARANCE FROM NACO-ETHICS COMMITTEE

SECTION 1: DETAILS OF APPLICANT

NAME: Prof/Dr/Mr/Mrs/Miss/Ms		**Signature**
Designation		
IF STUDENT/FELLOW (Tick the appropriate code)	**YES/NO**	
Degree Applicable (Masters/M.Phil/PhD)		
Principal Investigator (Name, Designation, Organisation, Contact details)		
Co-Investigators (Name, Designation, Organisation, Contact details)		
Institution/Organization where applicant registered/employed and full address		
***Please note that proposal should have signatures from all study investigators**		

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publication limited to previous 5 years)

SECTION 2: PROJECT DETAILS

1. TITLE OF PROJECT in full (do not abbreviate)	
2. Type of Study : Biomedical & Clinical Research=1 Social Science/ Behavioural Research=2 Epidemiological Research=3 Operational Research=4	
3. Status of Review: 1st Review ☐ 2nd Review ☐ 3rd Review ☐	
4. Funding Support/ Source : 1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐ b) Private ☐ Specify details	
2. International Government ☐ Private ☐ UN agencies ☐ Specify details	
3. Industry National ☐ Multinational ☐ Specify details	
5. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes/No
6. Contact Address of Sponsor/ Funding Source:	
7. Proposed Total Budget (INR) for the study:	
8. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale, study duration (Attach sheet with maximum 500 words):	
9. Subject selection:	
i. Number of Subjects :	
ii. Duration of study :	
iii. Will subjects from both sexes be recruited	Yes / No
iv. Inclusion / exclusion criteria given	Yes / No

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects (Tick the appropriate response) involved in the study

PLHA
Pregnant women
Children
HRG
Orphan
Illiterate
any other (specify)
(Mentally challenged)

10. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Anonymous/unlinked data ☐

ii. Confidential handling of data by staff	Yes	No

11. Collection of biological/ hazardous materials

i. blood	Yes	No
ii. body fluids If yes, specify _____	Yes	No

12. Consent :

*Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	e.g. genetic basis for drug development	

*If written consent is not being obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐

Any other (specify)

13. Assent :

*Written ☐ Oral ☐ Audio-visual ☐

i. Assent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that assent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Assent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	e.g. genetic basis for drug development	

*If written assent is not being obtained, give reasons:

ii. Who will obtain assent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐

Any other (specify)

14. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
15. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
iii. Is there any intervention under the study? **If Yes,** Follow-up ☐ Side effects ☐ Adverse events ☐		
iv. Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
16. Data Monitoring i. Has provision been made for data monitoring and security?	Yes	No
ii. Is there a plan for interim analysis of data?	Yes	No
iii. Is there a plan for reporting of adverse events?	Yes	No
17. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and purpose:	Yes	No

18. Is there compensation for medical care? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
19. Do you have conflict of interest? **(financial/non-financial)** **If Yes, specify :**	Yes	No

Checklist for attached documents:

Project proposal – 10 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Participant information sheet	☐
Informed Consent form	☐
Assent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of questionnaire	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐

Signature of Applicant

Countersignature of PI/ HOD
(in case of student/ fellow)
Place:
Date: