NATIONAL AIDS CONTROL ORGANISATION

(Monitoring, Evaluation and Research Division)

APPLICATION FORM FOR ETHICAL CLEARANCE

SECTION 1: DETAILS OF APPLICANT

NAME: Prof/Dr/Mr/Mrs/Miss/Ms	
Professional status	
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	
Whether member of NIIHAR	**YES/NO**
If yes Quote ID No	

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 Research=2 Epidemiological Study=3 Policy Management Study=4		
3. Status of Review:	New	Revised	
4. Sponsor Information : 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:			
7. Total Budget (INR):			
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 (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)

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

10. Privacy and confidentiality

i. Study involves - Direct Identifiers
Indirect Identifiers/coded
Anonymous/delinked

ii. Confidential handling of data by staff	Yes	No
11. Use of biological/ hazardous materials	Yes	No
i. Use of blood	Yes	No
ii. Use of body fluids	Yes	No

12. Consent :

*Written Oral Audio-visual

i. Consent form : (tick the included elements)

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

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI Nurse/Counsellor
Research staff
Any other (specify)

13. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
14. 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 a benefit a) to the subject ? Direct Indirect b) Benefit to society		
15. 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
16. Is there compensation for participation? **If Yes,** Monetary In kind Specify amount and purpose:	Yes	No
17. Is there compensation for medical care? **If Yes,** by Sponsor by Investigator by insurance by any other company	Yes	No
18. Do you have conflict of interest? **(financial/nonfinancial)** **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
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
(incase of student/fellow)
Place:
Date: