T-11020/11/2020-NACO (R&D)
Ministry of Health and Family Welfare
National AIDS Control Organisation

6th & 9th Floor, Chanderlok Building
36, Janpath, New Delhi – 110001
Dated the 11th March 2020

OFFICE MEMORANDUM

Subject: Regarding requests for research proposals/ projects pertaining to HIV/AIDS - reg.

This is with reference to the requests received by NACO and SACS from various stakeholders for permission and approvals to undertake research projects pertaining to HIV/AIDS.

In order to streamline the process, Standard Operating Protocols have been developed for handling such requests, routinely received in NACO and SACS. It is requested that compliance to the same may be strictly ensured.

This issues with the approval of Special Secretary & Director General, NACO.

Encl: SOPs pp. 1-4

(Dr. Shobini Rajan)
Assistant Director General (SI)

To:

Heads of Divisions, NACO
Project Directors, State AIDS Control Societies
NIIHAR institutes
Development and Implementing partners

Copy for information to:

1. Sr. PPS to Special Secretary & DG (NACO & NTEP)
2. PPS to Joint Secretary (NACO)
3. ECD and IH Divisions, ICMR, Delhi

Ministry of Health & Family Welfare
Government of India
National AIDS Control Organisation
(Strategic Information-Research & Evaluation)

Standard Operating Guidelines for Research Proposals/ Projects submitted to NACO/SACS

The National AIDS Control Programme (NACP) primarily undertakes research relevant to the programme and that address operational issues, gaps and provides solutions contextualized to the local settings, geographies and populations. National AIDS Control Organisation receives requests for approvals, permission to undertake studies/ projects at NACO facilities. In order to streamline the process to address varied requests for approvals and permission, Standard Operating Guidelines (SOP) for research proposals/ projects submitted to NACO, have been prepared. All applicants need to ensure compliance to the same before submitting the request to NACO.

Requirement and process of review and approval for each type of request is highlighted below:

S.N.	Type	Documents required	Process of approval	Role of NACO
A	NACO funded			
1	Funded by NACO	Proposal (technical & financial) submission in NACO format along with cover letter	Submission to Head, SI-Research & Evaluation Division with a cover letter indicating nature of study proposed, purpose of request, duration, funding source and budget	Approval by Competent authority at NACO, Letter of support
		Study instruments (quantitative & qualitative)	Approval by TRG	
		Participant Information Sheet and Informed Consent Form	Approval by NACO Ethics Committee	
		Local IRB approval	Administrative approval	
		Undertaking on Data use and Confidentiality	IFD approval	
		Once project is approved and undertaken, submission of Quarterly Progress Reports, Annual Reports, Draft Report, Final Report, Manuscript from research projects, abstracts from research projects, deliverables as per signed	MoU signing	
			Quarterly Progress Report	
			Progress reports tabled in TRG on Research/ NACO Ethics Committee	

S.N.	Type	Documents required	Process of approval	Role of NACO
		MoU		
B	**Funded by ICMR and other government institutes**			
1	ICMR funded, projects funded by medical colleges	Proposal (technical and financial) along with cover letter	Submission to Head, SI-Research & Evaluation Division with a cover letter indicating nature of study proposed, purpose of request, duration, funding source and budget	Approval by Competent authority at NACO, No Objection letter
		Study instruments (quantitative & qualitative)	Administrative approval	
		Participant Information Sheet and Informed Consent Form	Quarterly Progress Report	
		Approval by Scientific Advisory Committee of the institute	Progress reports tabled in TRG on Research/ NACO Ethics Committee	
		Local IRB approval		
		Letter by funding agency		
		Undertaking on Data use and Confidentiality		
C	**Funded by Development Partner/ International Organisation**			
1	Proposals funded by Development & implementing partner	Proposal (technical and financial) along with cover letter	Submission to Head, SI-Research & Evaluation Division with a cover letter indicating nature of study proposed, purpose of request, duration, funding source and budget	Approval by Competent authority at NACO, Letter of support
		Study instruments (quantitative & qualitative)	Administrative approval	
		Participant Information Sheet and Informed Consent Form	Quarterly Progress Report	
		Approval by Scientific Advisory Committee of the institute	Progress reports tabled in TRG on Research/ NACO Ethics Committee	
		Local IRB approval		
		Letter by funding agency		
		Undertaking on Data use and Confidentiality		
2	Referred by Health Ministry's Screening Committee	As per HMSC process	HMSC approval on the project	Approval by Competent authority at NACO, Letter of support

S.N.	Type	Documents required	Process of approval	Role of NACO
D	**Fellowships/ grants/ Thesis requests**			
1	Fellowships, government grant	Proposal (technical and financial) along with cover letter	Submission to Head, SI-Research & Evaluation Division with a cover letter indicating nature of study proposed, purpose of request, duration, funding source and budget	Approval by Competent authority at NACO, No Objection letter
		Study instruments (quantitative & qualitative)	Administrative approval	
		Participant Information Sheet and Informed Consent Form	Quarterly Progress Report	
		Approval by Scientific Advisory Committee of the institute	Progress reports tabled in TRG on Research/ NACO Ethics Committee	
		Local IRB approval		
		Letter by funding agency		
		Undertaking on Data use and Confidentiality		
2	PG/MD/MPhil/PhD/Post doctoral thesis			
a.	Pertaining to one or two States	Proposal (technical and financial) along with cover letter	Submission to Project Director, SACS with a cover letter indicating nature of study proposed, purpose of request, duration, funding source and budget	Approval by Competent authority at SACS, No Objection letter
		Study instruments (quantitative & qualitative)	Administrative approval at SACS level	
		Participant Information Sheet and Informed Consent Form	Quarterly Progress Report to SACS	
		Approval by Scientific Advisory Committee of the institute		
		Local IRB approval		
		Letter by funding agency		
		Undertaking on Data use and Confidentiality		
b.	Pertaining to multiple sites/	Proposal (technical and financial) along with cover	Submission to Project Director, SACS with a cover letter	Approval by Competent

S.N.	Type	Documents required	Process of approval	Role of NACO
	multi-centric	letter	indicating nature of study proposed, purpose of request, duration, funding source and budget	authority at NACO, No Objection letter
		Study instruments (quantitative & qualitative)	Administrative approval at SACS level	
		Participant Information Sheet and Informed Consent Form	Quarterly Progress Report to SACS	
		Approval by Scientific Advisory Committee of the institute		
		Local IRB approval		
		Letter by funding agency		
		Undertaking on Data use and Confidentiality		
E	**Miscellaneous**	Proposal (technical and financial) along with cover letter	Submission to Head, SI-Research & Evaluation Division with a cover letter indicating nature of study proposed, purpose of request, duration, funding source and budget	Approval by Competent authority at NACO, No Objection letter
		Study instruments (quantitative & qualitative)	Administrative approval	
		Participant Information Sheet and Informed Consent Form	TRG on Research and/or NACO Ethics Committee, if required	
		Approval by Scientific Advisory Committee of the institute	Quarterly Progress Report	
		Local IRB approval	Progress reports tabled in TRG on Research/ NACO Ethics Committee	
		Letter by funding agency		
		Undertaking on Data use and Confidentiality		