



**N.K.P. Salve Institute of Medical Sciences & Research Centre and
Lata Mangeshkar Hospital**
Digdoh Hills, Hingna Road, Nagpur – 440 019

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No. NKPSIMS & RC and LMH/ Dean/Estb/140 /2024 Date: 14th March, 2024

C I R C U L A R

WITH REFERENCE TO CIRCULAR NO. NKPSIMS & RC AND LMH/ DEAN/ESTB/ 19/2024, DATED 5TH JANUARY, 2024, FOLLOWING ARE THE REVISED GUIDELINES FOR PREPARING AGREEMENT AND FINANCIALS FOR NEW CLINICAL TRIALS IN N.K.P. SALVE INSTITUTE OF MEDICAL SCIENCES & RES. CENTRE AND LATA MANGESHKAR HOSPITAL, DIGODH HILLS, NAGPUR.

These guidelines aim to ensure transparency, compliance and effective collaboration between all stakeholders involved in the trial with effect from 01/03/2024 onwards.

1. Draft Agreement Approval Process:

Prior to the commencement of the clinical trials, the draft agreement will be thoroughly discussed by the Principal Investigator (PI) with the Dean, Medical superintendent, Directorate of Research (DoR) and the Finance representative to ensure alignment with institutional policies and financial considerations . Mr. Harpreet Singh will be responsible person for supervising finances in this centralized system as directed by Director (Audit).

2. Budget Approval and specification:

The agreement will clearly specify the approved budget for the clinical trials, Budget details, Including specific amounts allocated for various components, will be detailed and subject to approval by the Dean. Tripartite or Quadripartite agreement involving Clinical research organization/sponsor, Dean, Site management organization and/or Principal investigator (PI) will be done

3. Funds of Institutional ethics committee :

Fees of institutional Ethics Committee will be directly transferred to IEC account of NKPSIMS & RC and LMH as per IEC SOP.

4. When SMO (Site management organization) is involved (Clinical Trial through SMO) :

All approved funds for the clinical trials as outlined in the clinical trial agreement will be transferred to the account of SMO with application of Good and Services Tax (GST). Invoices for the same will be raised by SMOs to the CRO/Sponsor. As per the agreement, SMO after deduction of the amount of GST and SMO Share (70%) including Patient's conveyance allowances, Investigation cost, Archival Charges, hospitalization expenses if any, will transfer remaining (30%) funds to the bank account of NKP Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital on an



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immediate basis. Sharing of Funds between PI and SMO will be as per agreed Memorandum of Understanding (MOU) between them with institutional head also being one of the signing authorities in this MoU.

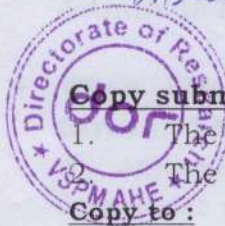
5. **When SMO (Site management organization) is not involved :** All approved funds for the clinical trials as outlined in the clinical trial agreement will be directly transferred to the bank account of NKP Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital. NKPSIMS & RC and LMH will then transfer funds to principal investigator within 7 working days after deduction of its institutional overhead expenses (IOH). Patient's conveyance allowance, Investigation cost, Archival Charges, Clinical Research Coordinator fees if mentioned in the trial budget will be reimbursed to PI on an actual basis after providing invoices.

6. Sharing Ratio :

The Standard sharing ratio will be 30:70 with 30% allocated to NKP Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital as institutional overhead expenses (IOH) and 70 % to the Principal Investigator /SMO. The Sharing ratio may be subject to change in certain circumstances with prior permission of the Dean as outlined in the agreement. Recurring expenses like required equipments for trial, stationary, investigation costs, procured equipments etc will be borne by Principal Investigator / S.M.O as per the agreement.

Copy to
Dr. Sushil Pande

Dr. Kajal Mitra
[Dr. Kajal Mitra]
Dean



Copy submitted for information to :

1. The Hon'ble Vice Chairman, VSPM AHE, Nagpur
2. The Hon'ble Treasurer, VSPM AHE, Nagpur

Copy to :

1. The Vice Dean (Administration), NKPSIMS&RC&LMH, Digdoh Hills, Nagpur
2. The Vice Dean (Clinical) & MS, NKPSIMS&RC&LMH, Digdoh Hills, Nagpur
3. The Project Director, VSPM AHE, Digdoh Hills, Nagpur
4. The Director, IQAC, NKPSIMS&RC&LMH, Digdoh Hills, Nagpur
5. The Director of Research, NKPSIMS&RC&LMH, Digdoh Hills, Nagpur
6. The Dy. Medical Superintendent, NKPSIMS&RC&LMH, Digdoh Hills, Nagpur
7. The HODs (Pre, para & Clinical) NKPSIMS&RC&LMH, Digdoh Hills, Nagpur
8. The Chief Account & Finance Officer, VSPM AHE, Digdoh Hills, Nagpur
9. The Finance Head (Hospital), NKPSIMS&RC&LMH, Digdoh Hills, Nagpur

DEAN
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Of Med. Sciences & RC
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