

1. Definition of Principal Investigator (PI):

Principal Investigator for regulatory studies **will ALWAYS be regular/permanent faculty** of Seth GSMC & KEMH and have relevant qualification approved by Maharashtra Medical Council (except in case as mentioned in clause no. 2).

Principal Investigator for other studies/ non-regulatory studies can be regular / permanent faculty, Emeritus professor, or contractual faculty of Seth GSMC & KEMH. If the Principal investigator is an Emeritus professor or a contractual faculty of Seth GSMC & KEMH, then the Co-Principal Investigator or Co-Investigator HAS to be a regular / permanent faculty of Seth GSMC & KEMH and who will be responsible for the study oversight.

- a. For resident / post graduate students, Ph.D students, MSc students, nursing students, M.Sc. Pharma Medicine (MUHS) projects, PI will be his / her guide / teacher and should be a permanent faculty of Seth GSMC & KEMH.
- b. **Thesis / Dissertation of Wadia Maternity and Paediatrics**
Faculty from the Wadia hospital are also considered as faculty **from** Seth GSMC & KEMH. Hence faculties from Wadia can be PI for the thesis submitted by the postgraduate students of Wadia hospital, however the recruitment of patient should be from only Wadia and not from the Seth GSMC & KEMH. For dissertations from BJJWHC must be forwarded by HOD (Pediatrics) Seth GSMC.
- c. **For collaborative studies with NIRRH, NIIH, TMH or for studies of nursing students** from the colleges other than GSMC & KEMH, PI should be a regular / permanent faculty from Seth GSMC & KEMH.

2. Cap for active / ongoing regulatory trials as Principal Investigator (PI) and Co-Investigator (Co-I):

Principal investigator (**regular/permanent faculty** of Seth GSMC & KEMH) will have **ONLY** eight (8) regulatory trials approved by the IEC as PI and **ONLY** eight (8) regulatory trials approved by the IEC as Co-I.

With regards to exceeding this cap (applicable **ONLY for PI belonging to super specialty departments**), contractual faculty may be made the PI as per clauses stated below:



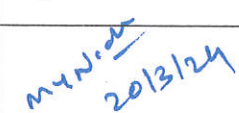
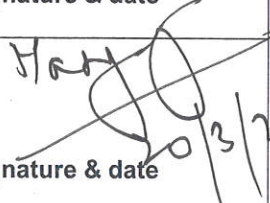
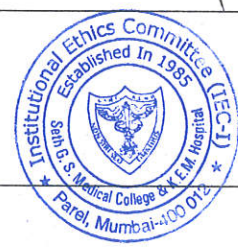

- i. should have completed ONE YEAR of service in this institute and this needs to be endorsed in writing by the HOD.
 - ii. HOD / regular/permanent faculty will be the CO-PI for such projects to support the contractual faculty working as PI for the given regulatory study.
 - iii. HOD / regular/permanent faculty to provide an undertaking stating that if the contractual faculty who is working as PI of the regulatory study leaves the institute then the regulatory study will be taken up by the HOD / regular/permanent faculty as PI.
 - iv. Duly signed undertaking from the contractual faculty which is forwarded or countersigned by permanent faculty stating that if he/she leaves the institute he/she ceases to be the PI of the project and the project cannot be transferred outside the institute.
 - v. The contractual faculty of super specialty department can have **ONLY** four (4) regulatory trials approved by IEC as PI and **ONLY** four (4) regulatory trials approved by the IEC as Co-I.
3. For all types of studies and for both permanent and contractual faculty as PI or Co-I to note that the study belongs to the institution and will stay with the institution whenever the contractual or permanent faculty leaves the institution. When the permanent or contractual faculty as PI or Co-I leaves the institute he / she ceases to be PI or Co-I in the project.
4. **If PI fails to submit the reply to 1st query letter** for the new project which is under review with IEC **within 180 days for regulatory trials:**
- a) Before the expiration / termination of validity of the query letter, an extension request should be submitted to IEC before the end of 180 days (are counter from the date mentioned on the query letter). If an extension request is not received in the timeline, then the project file will be shredded and declared closed for IEC records.

- b) If PI wishes to reply to the queries or re-opening of the trial file AFTER 180 days but within one year from the date of receipt of query letter, PI should re-submit the entire project and related documents (day 181 to day 365 from the date of the receipt of the query letter) along with 50% of the prevailing protocol review processing fees with TDS 10%. (project registration number will continue to be the same).
- c) If PI wishes to reply to the queries or re-opening of the trial file after 365 days, PI should re-submit the entire project and related documents along with 50% of the prevailing protocol review processing fees with TDS 10%. On resubmission the project will receive a new registration number.

5. If sponsors are unable to submit the entire insurance policy due to any reason:

As per NDCT rules 2019, an insurance policy is an essential document to be reviewed by the IEC members. However, if sponsors are unable to submit the entire insurance policy due to confidentiality or any other issues, then they should submit an undertaking stating the following: Sponsor XXXX acknowledges the fact that submission of a copy of entire Insurance Policy is one of the required documents as per Table I of Third Schedule of NDCT, Rules 2019. In line with this, the sponsor has procured insurance coverage policies and has submitted a valid insurance certificate. The sponsor is not in a position to share the entire insurance policy document due to Reasons. Sponsor assures that a valid policy in line with Indian Insurance Regulations is available and they commit to provide complete medical management and compensation in line with applicable NDCT, Rules 2019.

This undertaking must be provided on the sponsor letter head.

Prepared by	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	<div style="text-align: right;">  Signature & date 12/3 </div>
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Approved by	Dr. Manju Sengar, Chairperson, IEC-I	<div style="text-align: right;">  Signature & date 20/3/2024 </div>
Accepted by	IEC-I	
<div style="text-align: right;">  Signature and date Dr. Sangeeta Ravat, Dean, Seth GSMC and KEMH </div>		