VARDHMAN MAHAVIR MEDICAL COLLEGE
& SAFDARJUNG HOSPITAL
Ministry of Health & Family Welfare, Government of India, New Delhi

INSTITUTIONAL ETHICS COMMITTEE
IMC SJH

SOP 08	Title: Project submission and Review process (including for Clinical Trials)
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I. PURPOSE

A. To define the process for writing and submitting research projects/proposals to the Institutional Ethics Committee, through the Research Cell at VMMC & Safdarjung Hospital.
B. To ensure that the activities of the Research Department align with relevant regulations and guidelines.
C. To ensure that the activities of the Medical Research Council and Institutional Ethics Committee are aligned and coordinated for smooth flow of the processes.

II. APPLICABLE REGULATIONS AND GUIDELINES

1. Schedule Y (Drugs and Cosmetics Act-1940; amendment 20th January 2005).
2. ICMR's National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017).
3. Indian GCP Guidelines (2001).
4. WHO Operational Guidelines for Ethical Review Committees that Review Biomedical Research (2000).
5. International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996)
6. Declaration of Helsinki

III. RESEARCH PROPOSAL SUBMISSION

A. General instructions

1. Projects can be submitted by any faculty or PhD scholar of VMMC & SJH, on all working days to the Academic Section in VMMC building between 9.00 Am and 4.00 PM.
2. Multi-disciplinary projects involving several departments of VMMC & SJH are encouraged, as Co-I or Co-PI.
3. The research projects shall be forwarded by the respective Head of department. One Hard copy of the project/research proposal is to be submitted in the Medical Research Council (MRC), along with a soft copy of the same.
4. Projects submitted will be considered on first come first served basis. The staff in the MRC will note the date of submission and provide a Project Number to the Investigator.
5. A non-refundable fee of Rs 50,000 (Rupees fifty thousand) shall be levied for sponsored projects/drug/clinical trials, except projects submitted under rule 5.
    i. The fee shall be paid in the form of demand draft favouring "VMMC and Safdarjung Project".
    ii. The fee is to be paid at the time of submission of the project.
    iii. The demand draft must be valid for 75 days (Seventy Five days) at the time of submission.
    iv. Projects will not be accepted if fee is not paid at the time of submission of the project.
6. A non-refundable fee of Rs 15,000 (Rupees fifteen thousand) shall be levied for considering every application for amendment(s) in approved project involving drug trial.
    i. The fee shall be paid in the form of demand draft favouring "VMMC and Safdarjung Project".
    ii. The fee is to be paid at the time of submission of the application for amendment.
    iii. The demand draft must be valid for 75 days (Seventy Five days) at the time of submission.
7. A non-refundable fee of Rs 6,000 (Rupees five thousand) shall be levied for projects sponsored by ICMR/DST/CSIR/DBT and other Govt. institutions.
    i. The fee shall be paid in the form of demand draft favouring "VMMC and Safdarjung Projects fund".

ii. The fee is to be paid after the project is approved by the IEC and the sponsoring authority but before initiating/starting the project.
iii. The demand draft must be valid for 75 days (Seventy Five days) at the time of submission.
iv. Approval for the project will be deemed to be withdrawn if the project is initiated/started before the fee is paid.

8. A non-refundable fee of Rs 1,000 (Rupees one thousand) shall be levied for considering every application for amendments in approved project sponsored by ICMR/DST/CSIR/DBT.
   i. The fee shall be paid in the form of demand draft favouring "VMMC and Safdarjung Project fund".
   ii. The fee is to be paid at the time of submission of the application for amendment.
   iii. The demand draft must be valid for 75 days (Seventy Five days) at the time of submission.
9. No fee shall be levied for thesis/research projects of students.
10. No fee shall be levied for projects that are not sponsored or funded by any agency.

B. Project review process

a. Only projects that are complete in all respects and the requisite fee paid (if applicable) will be placed for review by the Academic Section.
b. The research projects will be reviewed by the members constituting the Medical Research Council, (MRC) to ensure compliance with established norms and guidelines and to review the content of the projects. This will be done on a day and time fixed in advance, and informed to the investigators.
c. Principal Investigator of the project or in case of multi-centre projects the Principal Investigator at VMMC & SJH, shall be present during the review of his/her project. The PI may be asked to present a brief summary of the project and/or provide clarification of any queries raised by member(s).
d. The decision of the Medical Research Council after review of the project shall be in one of the following categories:
   i. Approved
   ii. Revision with minor modification(s)
   iii. Revision with major modification (s)
   iv. Not approved
e. Letter communicating the decision of the MRC will be issued **within seven working days after the meeting.**
   i. Project which falls in the category of "Revision with minor modification(s)" has to be re-submitted to sub-committee (constituted by the Principal), after incorporating the modifications suggested by the MRC. Ordinarily, if the sub-committee certifies that the modifications have been incorporated, the project shall deemed to be approved and shall not be taken up by MRC again. However, in some cases the sub-committee can refer the project to MRC, giving reasons for doing so, for approval of the project.
   ii. Project which falls in the category of "Revision with major modification(s)" has to be re-submitted to sub-committee after incorporating the modifications suggested by the MRC. The sub-committee will review the resubmitted project and refer it to the MRC along with its remarks for final decision.
f. The MRC can withdraw its approval to any research projects if it is convinced that the continuation of the research poses undue threat to safety of the subjects, or there is violation of terms and conditions of the approval, or violation of undertaking given by the Principal Investigator.
g. Once the MRC has approved a research project, it will forward the project to the Principal for perusal & final review. From the Principal's office the projects will be sent to the Medical Superintendent's office for dispatch of all the projects to the IEC for review of ethical aspects.

h. The entire process of approval of a research project is expected to be completed within four weeks from the time of submission of the project**.**

IV. INSTITUTIONAL ETHICS COMMITTEE (IEC) CLEARANCE

1. The IEC will meet roughly once a month to review the ethical aspects of all projects it receives from MRC.
2. If there are no ethical issues, the projects will be cleared and IEC certificates issued. If there are ethical issues, the same will be communicated to the PIs, who will then clarify or rectify the issues and re-submit to IEC Sub-committee for review.
3. Finally, the certificates for IEC clearance will be issued by the IEC, after which the PIs are free to begin their project work.
4. A 6 monthly report of the progress of the project shall be submitted by all PIs till the end of the project. The format available with the IEC may be used for this. At the end of the research project, a final report shall be submitted by all PIs to the MRC.
5. The entire process of approval of a research project is expected to be completed within four weeks from the time of submission of the project.

V. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

1. The PI will be solely responsible for the training of staff participating in the project.
2. The PI will ensure that the recruitment of the research team is as per the prevailing guidelines and they maintain up-to-date CVs at all times.
3. The PI must stay updated with the latest regulatory amendments.
4. Compliance with FDA regulations for FDA-regulated studies is mandated.

VI. TRAINING OF MEMBERS OF RESEARCH CELL(MDRU) AND IEC

It is recommended that the members of both MRC and IEC undergo training/refresher training in GLP and GCP at least once every three years, if not earlier. The copies of the certificates must be available at the MRC/IEC office.

VII. RESPONSIBILITY AND UNDERTAKING

1. Co-investigators are expected to take responsibility for completing the proposed work if the PI is unable to do so for any reason.

2. An undertaking is required from the PI that the same proposal has not been submitted or funded by any other funding agency.

VIII. WRITING TIPS FOR RESEARCH INVESTIGATORS

1. Specify the type of study.
2. Be clear and concise
3. Avoid duplicating existing studies
4. Provide a valid hypothesis aligned with objectives and outcomes.
5. Describe a methodology that achieves the objectives.
6. Include appropriate statistical methods
7. Ensure feasibility with current resources.
8. Relate to health priorities
9. Demonstrate translational value
10. Address potential harm to people or the environment
11. Specify PI and Co-PI responsibilities
12. Include novelty in the project
13. Provider proper justification for the budget.

IX. PROCESS FOR CLINICAL TRIALS

The process to be followed for submission of Clinical trials will be the same as described in the above sections. But, in addition to these, the following points are applicable for clinical trials-

1. In how many clinical trials the applicant is already nominated as PI or Co-PI
2. Clarify how the applicant is managing these trials along with his/her clinical work

3. Provide an undertaking that engagement in this clinical trial will not impinge on / hamper the clinical responsibilities of the applicant.

Special Review Conditions

For ICMR/ DST/ DBT/ Govt Agency funded project

The IEC shall issue only a provisional approval certificate in cases of projects which involve funding by any government agency viz. ICMR/DBT/DST and the final approval shall only be granted if the project is approved by the Govt agency including the funding for the project

Review of projects involving foreign collaborations

All projects involving foreign collaboration shall be subject to the Guidelines issued by the Indian Council for Medical Research (ICMR) i.e. GUIDELINES FOR INTERNATIONAL COLLABORATION / RESEARCH PROJECTS IN HEALTH RESEARCH

The PI shall be responsible for strict compliance of the ICMR guidelines

Review of similar projects to avoid duplication/plagiarism

The IEC shall reserve the right to reject any project which it deems to have been duplicated or plagiarised. The IEC shall give reason to the investigators for any such rejection

Appellate Authority

All disputes arising out of the review process shall be subject to the final discretion of a committee constituted by the Medical Superintendent, Principal & the Member Secretary. IEC of VMMC & Safdarjung hospital

The decision of the Committee shall be final and binding on the investigators as well as the IEC.