AX05/SOP 08/V1.1Guidelines for Investigators

- All the studies qualifying as 'clinical research' need to be submitted for the Institutional Ethics Committees review.
- An Investigator planning to conduct a research study involving human participants; funded by Government agencies and Pharmaceutical companies at Dr.Vasantrao Pawar Medical College Hospital and Research Centre, Nashik will need an approval by the Institutional Ethics Committee (IEC) before commencing a study.
- Research studies which are undertaken as dissertation projects (postgraduate students: MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), research projects of undergraduate students and investigator initiated research studies which are self funded and those funded by Dr.Vasantrao Pawar Medical College Hospital and Research Centre, Nashik will need an approval by the Institutional Ethics Committee (IEC) before commencing a study.
- Location and Office Address (current): Institutional Ethics Committee (IEC), Dr.Vasantrao Pawar Medical College Hospital and Research Centre, Vasant dada nagar, Adgaon, Nashik – 422003
  Telephone no: +91 253 2220500, Ext : 1274
  Email id :iec@drvasantraopawarmedicalcollege.com
- The IEC office hours for submission of documents, enquiries and telephonic communication with the IEC staff are as follows:
  Monday to Friday - 10.00 a.m. to 4.00 p.m.
  Saturday - 10.00 a.m. to 1.00 p.m.
  The office will remain closed on Sundays, all public holidays
- There will be no meetings held in the month of May and November (during college vacations) except during emergency and epidemics/pandemics. In case a meeting is to be held during vacation due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.
- The clinical trial (Any investigation in human research participants intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an

investigational product(s) with the object of ascertaining its safety and/or efficacy [ICH-GCP]) must be registered with the Clinical Trial Registry of India (CTRI) or any other WHO platform registry and a copy of the documentation of registration must be provided at the time of submission of a new study proposal for review.

- General responsibilities of PI and Co-PI

1. **MMC/MCI/NMC:**

- Investigators involved in the trial are competent having a valid medical degree registered with the Medical Council of India (MCI) / State Medical Council Updated and signed CVs: (Annexure 8: AX08/SOP 08/V1.1: Format of Curriculum Vitae/Bio data of Investigators)
- Investigators responsible for conduct of clinical trials are adequately qualified and experience.

2. **GCP:**

- Investigators should have knowledge about clinical trial process, ethical issue and applicable rules and regulation ensuring data integrity and protection of subject rights, safety and wellbeing.
- Investigators should be GCP trained regularly at the interval of three years and GCP training certificate should be provided to the IEC at the time of submission of a new study proposal / prior to initiation as applicable.

3. **SOPs of IEC:**

- Investigators should follow documented procedure i.e. Standard Operating Procedures (SOPs) of IEC in compliance with the regulation and the approved protocol or informed consent, safety reporting management, delegation of responsibilities and training, investigational product, clinical trial documentation, record retention, archival and destruction.

Investigators site specific SOPs for regulatory studies:

- Investigator should prepare site specific SOPs which should be approved by the IEC and one copy should be handed over to the IEC for its records. Site specific SOPs should also cover the following elements related to the conduct of the clinical trial.
    - Updated investigators Brochure and clinical trial oversight plan

- SOP/Policy document to ensure continuity of trial in case of staff and investigator attrition
- Clinical trial site shall have a policy of investigators handling over the trial case he /she to leave investigator will continue to be responsible for the trial until such time another investigator takes over the trial. Authorized person from the site shall communicate with the sponsor and ethics committee if needed. There should be back up research staff to ensure that recruited subject's rights safety and wellbeing is not compromised.

- The following steps need to be followed by investigators while submission of a New study proposal to the IEC

I . Prior to approval of a research study

- Only PI can forward the Project to IEC Admin.
- The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the ICMR 2017 Guidelines. The section should include the following aspects which may be stated in the Ethics Section or elsewhere in the protocol:
  - A statement saying that the study will be conducted in adherence to relevant national/international laws.
  - Policy regarding autonomy (voluntariness, right to withdraw).
  - Confidentiality
  - Recruitment policy ensuring equitable enrolment
  - Protection of vulnerable participants
  - Process of obtaining informed consent
  - Policy regarding treatment of study related injury, compensation for study related injury and compensation for participation.
  - Policy regarding dissemination of data, presentation of data, publication.
- Incompletely filled forms / forms without signatures / proposals will not be accepted and same will be conveyed to the PI
- Decision on type of review:

- Member secretary will review the protocol and related documents and will take the decision regarding the type of the review required for the particular protocol as follows:
  a) Full Board Review (refer SOP 08-A)
  b) Expedited Review (refer SOP 08-B)
  c) Exempt from Review (refer SOP 08-C)

- An investigator may refer to the SOP. No. 18 for 'Request for Waiver of Written Informed Consent' whenever necessary.

- The processing fees shall be collected only once at the time of submission of the project. The sponsored projects fees will be accepted by cheque / demand draft/NEFT which will include the tax, drawn in the name of 'Dean, Dr. Vasantrao Pawar Medical College, Nashik'.
  Note: * For Pharmaceutical Industry and Government Sponsored projects Annual Review Fee is applicable as mentioned.
  - Refer **AX03/SOP02/V1.1 : Finances Related to Ethics Committee Activities and Functioning**

Online payment details for funded/ sponsored studies:

Account Name: Dean, Dr. Vasantrao Pawar Medical College, Nashik.
Bank Name: IDBI Bank M.G.Road. Nashik
Account No: 0458104000255486
IFS Code: IBKL0000458
MICR Code: 422259003

1. PI to notify the IEC regarding sanction and receipt of funding.

2. Failure to do so will result in disciplinary action.

3. Upon on receipt of funding PI must follow the procedures prescribed for Sponsored or Govt. studies.

- An investigator may be invited (telephonically/ through written communication) to the IEC meeting to discuss issues related to the study proposal.
- For clinical study planned on an "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator, or sponsor. This is in accordance with the ICMR 2017 guidelines.
- An investigator is expected to submit reply to the 1st query sent by the IEC within 180 days of date of receipt of the letter. The reply to subsequent query letters must be submitted within 60 days of receipt of the query letter. In the absence of any response, the project will be declared closed for the IEC office records. In case of any valid reason IEC must be communicated within the said period to increase the validity period.

II . Once approval for a study is granted

- An approval will be granted for the entire duration of the study.
- For all regulatory and pharmaceutical sponsored clinical trials it is the responsibility of the principle investigator that for studies which will continue for more than six months, a periodic review report / continuing review report needs to be submitted (within 1 month of the due date i.e. 6 months from the date of approval).
- Annual status report for regulatory and pharmaceutical sponsored clinical trials should be submitted one month before end of validity along with annual review fees.
- For studies approved during epidemics status update should be submitted at 45 days after approval (continuation review fees not applicable).
- For Biomedical Health Research (BHR) it is the responsibility of the principle investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval)
- For all projects sponsored by pharmaceuticals, the annual review fees will be Rs. 20,000 ± 18% GST, for the Government sponsored projects, the processing fees will be Rs. 5,000 /project
- For academic (non- sponsored) projects no continuing review fee will be charged.

- The continuing review fees shall be collected annually from the date of approval (unless specified otherwise). The sponsored continuing review fees will be accepted by cheque / demand draft/NEFT which will include the tax, drawn in the name of 'Dean, Dr. Vasantrao Pawar Medical College, Nashik'.
- Submission of Study Related Documents for IEC review
    - Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations, termination) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review.
    - Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting and is sent to the IEC members at least 1-2 days in advance. Hence, all study related documents like answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) received within seven days and other types of documents within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next month's meeting for discussion (Exception - any matter which in the opinion of the IEC secretariat has direct bearing on the safety of the research participants such as SAE report, major protocol violation etc).
- Submission of Amended Protocol and Protocol Related Documents
    - All amendments to the approved research proposal (only one set) should be submitted to the committee for its review no later than 7 seven days prior to the date of forthcoming meeting.
    - No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).
    - A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents along with the **AX 02/ SOP 12/V1.1**
- Submission of Report of Protocol Deviations/ Violations in the study protocol

- Please use Annexure for submitting report of Protocol Deviations/ Non-Compliance / Violations. **AX 04/ SOP 12/V1.1**

- Submission of Report of Serious Adverse Events (SAEs)
  - Refer to SOP 15 V1.1
- Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.
- If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issues/ objections raised by the committee within twelve (6) weeks of the receipt of the committee's decision. In absence of appeal, the project will be declared closed for the IEC office records.
- Submission of continuing review report
  - Refer to **SOP 13/V1.1**

III. Upon completion of study

- Submission of Study Completion Report
- Refer to **SOP 16/V1.1**

IV. In case a study is not initiated or terminated

- Refer to **SOP 17/V1.1**