Bharati Vidyapeeth's (Deemed To Be University)

School of Physiotherapy

Sangli- Miraj Road, Wanlesswadi, Sangli-416416

INSTITUTION ETHICS COMMITTEE

(Responsibility, Composition and Procedures)

Chairperson	Dr. Shahaji Deshmukh
Co-ordinator	Dr. R. P. Limaye
Secretary	Dr. Sneha Katke
Members	HOD Medicine – Dr. Chidanand
	HOD Surgery – Dr. Vinod Prabhu
	HOD Ortho – Dr. Shrikant Deshpande
	HOD Pediatrics – Dr. Suhas Kumbhar
	HOD Obs/Gynac – Dr. Vidya Jadhav
Research Co-ordinator	Dr. Sunil Harsulkar
Legal Advisor	Dr. Pooja Narwadkar
Statistitian	Dr. Alka Gore

BVDU SOP INSTITUTION ETHICS COMMITTEE

(Responsibility, Composition and Procedures)

Purpose:

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the Ethics Committee for research on Human subjects in BVDU Medical College, Sangli. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian laws and relevant, National and International Guidelines.

Scope:

The SOP applies to all activities performed by the Ethics Committee for Research on Human Subjects, in BVDU Medical College and Hospital, Sangli.

Responsibility:

It is the responsibility of the Ethics Committee for Research on Human Subjects members and the Secretariat to read, understand, follow and respect the SOP set by the Ethics Committee for Research on Human Subjects.

To ensure that the research projects that are carried out in BVDU Medical College and Hospital, Sangli.

- Are sound in design, have statistical validity and are conducted according to the ICMR and ICH/GCP guidelines
- Do not compromise safety of the patients or volunteers
- Are conducted under the supervision of trained medical / bio-medical persons with the required expertise
- Include, solely, patients or participant who have given voluntary and informed consent

It may be ensured that no research project shall be / can be started unless Ethics Clearance / Approval is obtained and that no retrospective / post facto Ethics Clearance/ Approval can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

The committee expects from the investigators:

- A progress report on six monthly basis or more frequently as the committee feels it.

• A report of each serious event when observed during the conduct of the study
• To keep informed of amendments to any study related documents
• To keep informed of study discontinuation with reasons.

Composition of the Ethics Committee for research on Human subjects:

• The ECRHS will be established by the Head of the Institution (HOI).
• The ECRHS will be multidisciplinary and multi-sectoral in composition.
• The ECRHS will be composed of at least 7 and a maximum of 10 members.
• Out of total members minimum 2 members will be ladies

The members should be a mix of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.

• The members will have differing backgrounds as this would promote complete and adequate review of research activities commonly conducted at BVDU Medical College and Hospital, Sangli.
• The ECRHS will have representation that is varied in terms of gender, age and social background.
• The Composition may be as follows:

Chairperson (who will be a member not -affiliated to the institution)
One Member Secretary
One Joint Member Secretary (appointed if necessary)
One or more persons from basic medical science area
One or more clinicians from various departments
One legal expert or retired judge
One social scientist/ representative of non-governmental agency
One philosopher, ethicist or theologian
One or more lay person from community

• The ECRHS may appoint an alternate legal expert, lay person from community and a social scientist who can take part in the ECRHS activities in absence of regular members from the above specified categories. The requirement, appointment and terms of membership will be the same as described below.
• The ECRHS may have one/ more co-opted members who will be assigned a specific activity and will assist the member secretary. The requirement, appointment and terms of membership will be the same as described below.

• The ECRHS may invite member(s) of specific patient groups or other special interest groups for an ECRHS meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

Membership requirements:

• The Head of the Institute (HOI) is responsible for appointing new committee members. The Chairperson and ECRHS members can suggest names of potential members but the final decision will remain with the HOI.

• Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the ECRHS work.

• Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration.

• The ECRHS will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision. Members will be required to sign a confidentiality agreement at the start of their term.

Tenure of Membership:

• The tenure of Ethics Committee for Research on Human Subjects (ECRHS) members will be for a continuous period of three (3) years from the date of appointment.

• The ECRHS secretariat will initiate the process of filling up the forthcoming vacancies two months prior to the end of tenure of a member, The Chairperson will recommend names of individuals to the HOI. The HOI will select and appoint a member for the new tenure from the list provided by the ECRHS or otherwise. The retiring member will be eligible to be appointed for the new tenure any number of times.

Appointment of new members and alternate members:

a) The ECRHS members will be appointed by the HOI. New members will be appointed under the following circumstances:

1. When a regular member completes his/ her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements as required

b) New members will be identified by the Chairperson according to the requirement (i.e. as per the composition specified), membership requirement and provided the potential member fulfils the conditions of appointment as defined in this SOP after discussion by the ECRHS. The names of new members to be appointed may be suggested by the ECRHS members and the Chairperson to the Head of the Institution HOI. The final decision regarding appointment of members will be taken by the HOI.

c) Alternate member(s) will be appointed if deemed necessary by the HOI. The alternate member(s) will substitute a regular member and attend the meeting in absence of the regular member(s). The criteria for selection and membership requirements mentioned will be applicable to alternate members.

Resignation and Disqualification of Members:

• Resignation: An ECRHS member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

• Disqualification for conduct unbecoming of an ECRHS member: A member may be disqualified from continuance should ECRHS determine by a three-fourth majority specifically called for the purpose that the member's conduct has been unbecoming of an ECRHS member.

(i) The process will be initiated if ECRHS Chairperson or Member-secretary receives a communication in writing (provided by ECRHS member or a member of the public) alleging misconduct by a member.

(ii) The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of ECRHS could be questioned, the Chairperson may suspend the membership of the concerned ECRHS member till final decision is taken by ECRHS. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an ECRHS member and will not perform any duties of ECRHS member.

(iii) The Chairperson may call for a meeting of the ECRHS specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the ECRHS meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself/ herself.

(iv) The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.

• Disqualification for not attending ECRHS meetings: A member may be disqualified from ECRHS membership if the member fails to attend more than 3 regular consecutive ECRHS meetings without prior intimation.

The process conducted will be as follows:

(i) The member-secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the ECRHS.

(ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular ECRHS meeting

(iii) A written communication will be sent to the concerned ECRHS member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case.

Alternately, the concerned ECRHS member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the

Chairperson

(iv) The matter will be discussed and reviewed at the ECRHS meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

• The Chairperson or Member-Secretary will inform the ECRHS members about the cessation of membership by a confidential written communication to other members of ECRHS or at the next meeting of ECRHS.

Conditions of appointment:

Members and Independent consultants will be appointed to the ECRHS if they accept the following conditions.

• Willingness to publicize his/her full name, profession and affiliation.

• Willingness to record reimbursement received for work and expenses incurred, related to the ECRHS assignment and make these records available to ECRHS and/ or general public on request.
• Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.

Training of the ECRHS Members in Research Ethics:

• An individual selected as a new member of the ECRHS will be required to attend two meetings as an 'Observer' before being inducted as a member of the ECRHS
• Member-secretary or an ECRHS member will provide an introductory training to the new member.
• The ECRHS Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
• The ECRHS will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the ECRHS Members to the Institutional faculty members.
• The ECRHS may sponsor or reimburse the expenses of an ECRHS member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

Hierarchy:

• There will be one Chairperson, one Member Secretary. A Joint Member Secretary may be appointed amongst the members if necessary.
• The Chairperson will be the head of the committee. The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents and funds in the possession of the committee.
• Other ECRHS members will be regular committee members with equal ranking.
• The Chairperson will be appointed by the Head of the Institute,
• The Member-secretary, Joint Member-Secretary (if necessary) will be elected by and from amongst the ECRHS members for 3 years term. These may be re-elected any number of times.

Should they resign or be disqualified, the ECRHS members will elect a replacement for another term.

Chairperson

• The Chairperson will be appointed by the Head of the Institute,

• The Chairperson will not be affiliated to the institution.

• The Chairperson will be responsible for conducting committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.

• The Chairperson will preside over all elections and administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the ECRHS at various meetings and forums.

• The Chairperson will sign documents and communications related to ECRHS functioning.

• The Chairperson will delegate his/ her responsibilities to appropriate individuals in accordance with ECRHS SOPs

• In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

Secretariat

[1] The Secretariat will be composed of the ECRHS Member Secretary, ECRHS Joint Member Secretary (where applicable), the scientific officer/s the administrative Officer/s and other administrative supporting staff.

[2] The Member Secretary and the Joint Member Secretary (appointed if necessary) will be elected by and from amongst the committee members.

[3] The administrative staff of the Secretariat will be appointed by the ECRHS and they will be supervised by the Member Secretary.

[4] The Secretariat shall have the following functions.

Functions of the Member secretary

1. To receive research proposals
2. To organize an effective and efficient tracking procedure for each proposal received.
3. To prepare, maintain and distribute of study files.
4. To schedule and organize ECRHS meetings
5. To prepare and maintain meeting agenda and minutes.

6. To maintain ECRHS documentations and to archive them.
7. To communicate with the ECRHS members and applicants/ investigators.
8. To notify the Principal Investigator regarding ECRHS decisions related to the submitted research proposal.
9. To arrange for training of personnel and ECRHS members.
10. To organize the preparations, review, revision and distribution of SOPs and guidelines.
11. To provide necessary administrative support for ECRHS related activities to the Chairperson.
12. To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
13. To receive fees and issue official receipts for the same.
14. To delegate various responsibilities to appropriate and authorized individuals
15. To ensure adherence of ECRHS functioning as per SOPs

Functions of the Joint Member Secretary (whenever appointed)

The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.

Functions of the Scientific and Administrative Officer/s

1. To support the Member Secretary in executing functions of the ECRHS.
2. To perform any other functions as instructed by Member Secretary/ Chairperson.

Roles and Responsibilities of ECRHS members:

• To attend ECRHS Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
• To review, discuss and consider research Proposals submitted for evaluation.
• To monitor Serious Adverse Event reports and recommends appropriate action(s)
• To review the progress reports and monitor ongoing studies as appropriate.
• To evaluate final reports and outcomes.
• To maintain confidentiality of the documents and deliberations of ECRHS meetings.
• To declare any conflict of interest.
• To sign the Confidentiality/ Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

• To participate in continuing education activities in biomedical ethics and biomedical research. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the ECRHS secretariat
• To provide an updated CV when requested for by the ECRHS secretariat
• To carry out the work delegated by Chairperson, Member-secretary and Jt. Member secretary.
• To assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out ECRHS work as per SOPs

Quorum Requirements:

• Meeting will be held as scheduled provided there is quorum. For the ECRHS meeting, a quorum will consist of one pharmacologist, the social worker, a clinician, a lay person and the legal expert besides the Member Secretary and the Chairperson. All decisions should be taken in meetings and not by circulation of project proposals.

Honorarium to the Members/ Independent Consultants:

• Reimbursement of traveling expense, sitting fees for attending the ECRHS meetings and /or honoraria may be given to the ECRHS members/ office bearers/ Independent consultants and any other person authorized by the ECRHS.

Responsibilities of the Ethics Committee for Research on Human Subjects:

• The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
• The Committee will keep all information submitted to them confidential specially the proprietary information.
• The Committee will maintain concise but clear documentations of its views on the research proposal.
• The Committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year and will also review the final report of the studies approved by them.
• The Committee will participate in activities that promote ethical research in the institution and community.

• The Committee will participate in and organize programs aimed at educating and training community members, members of the public, investigators, ethics committee members in ethical research.

Prepare an annual activity report of the ECRHS for submission to the Head of the Institute

• The Secretariat will make a yearly activity report for submission to the Head of the Institute which will include the following elements:

a. A quantitative evaluation of the activities of the committee in a year

b. The list of the proposals reviewed in a year

c. Status of each study proposal

Offices/Conduct of the Meeting

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

Independent Consultants

IEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will not take part in the decision making process.

Application Procedure

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
2. All relevant documents should be enclosed with application.
3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co investigators/Collaborators should be forwarded by the Head of the Department.
4. The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
6. The decision of IEC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

Documentation

All research proposals should be submitted with the following documents:
1. Title of the project
2. Names of the PI and Co-investigators with designation.
3. Name of any other Institute/Hospital/Field area where research will be conducted.
4. Approval of the Head of the Department.
5. Protocol of the proposed research.
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow–up cards, etc. to be used in the study.
8. Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them.
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.
10. Any regulatory clearances required. Copy of clearances is obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
11. Source of funding and Budget along with the supporting documents.
12. Indemnity issues including insurance for the compensation to the participants etc.
13. An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Plans for publication of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.
16. Any other information relevant to the study.
17. Agreement to submit annual progress report and final report at the end of study.

18. The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

Review Procedure

1. Meetings of IEC shall be held on scheduled intervals as prescribed. Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

Element of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.
8. Patient information sheet and informed consent form in English/Hindi and local language.
9. Protection of privacy and confidentiality of subjects.
10. Involvement of the community, wherever necessary.
11. Protocol and proforma of the study including the consent form.
12. Plans for data analysis and reporting.
13. Adherence to all regulatory requirements and applicable guidelines.
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure.

Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.

i) PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.
ii) The final report of the completed study should be submitted by PI.
iii) The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.

Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device/Collaborative Trials

After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Dean, BVDU Medical College, Sangli with the counter signature of PI. The drug trial shall be

started by the PI after the agreement is signed by both the parties as well as DCGI and required regulatory approvals are available for the concerned trial.

Follow up Procedures

1. Annual report should be submitted by the PI on prescribed format along with comments.
2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
3. All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any amendment to the protocol should be submitted for approval.
6. Any new information related to the study should be communicated to IEC.
7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
8. Change of investigators should be done with the approval of IEC.

Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.

Updating IEC Members

1. All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.

2. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.

The schedules of submitting the proposal is as follows:

Submissions will be received on all days. Proposals received till 15th of any month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting.

All meetings of ethics committee will be held as far as possible on first Monday of Jan, Feb, March, April, May, August, September, October, November and December.

The committee will give its opinion on the project in writing in one of the following ways:

- Approval
- Disapproval
- Modification before approval
- Discontinuation of previously approved project

The chairman / member secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made / expedited review is required. This decision will be ratified at the next full committee meeting and minuted.

All documents pertaining to the Institution Ethics Committee will be held in the office of the Member Secretary of Institution Ethics Committee.

Glossary:

Confidentiality	Prevention of disclosure, to other than authorized individuals, of ECRHS/ information and documents
ECRHS	Ethics Committee for research on Human subjects is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial (at sites which do not have EC/EC not functional as per Schedule Y) and to provide public assurance of that protection.

Independent Consultants	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed

Dr. Sneha Katke Ph.D.
Member Secretary
BVDUSOP Ethics Committee
Sangli

References:

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000 www.who.int/tdr/publications/publications/)
International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 http://www.ich.org/LOB/media/MEDIA482.pdf
[2] CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm
[3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf
[4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm
[5] European Convention on Human rights and Biomedicine (1997). http://conventions.coe.int/treaty/en/treaties/html/164.htm

Annexure 1

The ECRHS Administrative Staff: Working Rules

[1] There will be administrative officer/s and attendant/s or helper/s who will help the ECRHS Chairperson and Member Secretary in executing functions of the ECRHS. Additional staff may be appointed and duties assigned; as and when deemed necessary by the ECRHS. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The decisions regarding need for appointment, eligibility criteria, job profile and remuneration will be

taken by the ECRHS members attending a regular ECRHS meeting and will be recorded in minutes.

[2] The administrative staff will be appointed by conducting formal interviews (to be conducted by 2 to 3 members of the ECRHS, designated by the Chairperson).

Permission of the MAEER, Pune (The MAEER manages the ECRHS accounts) shall be sought every time a new administrative staff member is to be appointed.

[3] The terms and conditions of the appointment shall be as follows:

The appointment will be on temporary basis. A monthly stipend will be given.

The amount of stipend will be decided by the ECRHS members. Since the posts are not government posts, the government service rules will not apply to them. The appointed staff will not get benefit of government employees. They will not get any preferential treatment and will not have right to the posts advertised by government.

[4] Duties of the Scientific Officer/s

- Receiving all research proposals.
- Numbering the proposals.
- Forwarding all proposals to committee members for review.
- Establishing time limits for receipt of reviewers' comments.
- Preparation of agenda for all committee meetings (of the ECRHS).
- Inviting experts from relevant therapeutic areas to the scheduled meetings.
- Notification of review outcome to investigators of research proposals.
- Preparation and circulation of minutes of the ECRHS (within 7 working days of the meeting).
- Reviewing project related correspondence submitted by the investigators to the ECRHS
- Retention and safekeeping of all records and documentation.
- Performance of other duties assigned by the Chairperson.

[5] Duties of the Administrative Officer/s

- Correspondence with the ECRHS members and external experts
- Correspondence with the investigators
- Arranging the ECRHS meetings
- Assisting in preparing agenda and minutes of the ECRHS meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files

[6] Duties of the Attendant/s or Helper/s

- Assisting the secretariat in arranging the ECRHS meetings
- Dispatching sets of study documents to ECRHS members and external experts
- Receiving the study related documents from and dispatching the ECRHS letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Correspondence with the ECRHS members and external experts

[7] The administrative staff will report to the Chairperson and/or Member Secretary.

[8] The office timing for the scientific officer and administrative officer will be 9 am to 4 pm or 9.30 am to 4.30 pm. The timing for attendant / helper will be 8.30am to 4.30 pm.

[9] The staff will avail 15 casual leaves and 15 privileges leave every year by making an application. The number of leaves granted per year can not be accumulated or carried forward to next year. A new staff member will be allowed to avail a casual leave 6 months after joining and privilege leave after completing one year. Leave applications will be maintained in the personal file of the staff members. The decision regarding granting a long leave to the staff will be taken at a regular ECRHS meeting by the ECRHS members.

[10] The pay revisions will be made according to the recommendations of the ECRHS. The recommendations regarding pay revisions will be discussed at a regular ECRHS meeting and will be recorded in minutes. The final decision regarding pay revision will be taken by MAEER, Pune.

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE

Submit fifteen (15) copies of the Research Project along with Covering letter and 'soft copy' on CD with the following information to the Member Secretary, Institution Ethics Committee**.** The Principle Investigator must submit protocol through Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the **Institution Ethics Committee** with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet*

(PIS), both in English and Hindi, in an **understandable layman's language** before it can be considered for placing before the Institution Ethics Committee. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all days. Proposals received till 15th of any month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible on first Monday of Jan, Feb, March, April, May, June, July, August, September, October, November, and December.

While submitting replies raised by the Institution Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethic Committee. Moreover if the approval is required in a particular format, the same may be submitted in a CD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes in a tabulated form and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

The research projects / proposal submitted should be as follows:

1. Full Title of Study:		
1a. Temporary Research Section Number for all clinical trials which are privately funded		
2. Name of Investigators / co-investigators (permanent Staff) with designation and departments 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____ (Expand if more co-investigators)	Signatures 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____	No. of projects already with investigator _____ _____ _____ _____
3. Objectives of the study	3.1_____ 3.2_____ 3.3_____	

	3.4_____ 3.5_____
4. Justification for conduct of this study	
5. Methodology	5.1. Number of Patients: 5.2. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 5.3. Exclusion criteria a)_____ b)_____ c)_____ d)_____ 5.4. Control(s) _____ 5.5. Study design _____ 5.6. Dosages of drug _____ 5.7. Duration of treatment _____ 5.8. Investigation specifically related to projects_____ 5.9 Permission to use copyrighted Questionnaire/proforma 5.10. Others _____
6. Permission from Drug Controller General of India (DCGI)	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:
7. Permission from DGFT if applicable	1. ☐ Required 2. ☐ Not required 3. ☐ Received 4. ☐ Applied when:
8. a) Safety measures for proposed interventions b) Results of relevant laboratory tests c) Result of studies in human	a)_____ b)_____ c)_____
9. Plans to withdraw standard therapy during conduct of research	☐ Yes ☐ No Remarks:_____
10. Plan for provision of coverage for medical risk (s) during the study period	

11. How you will maintain confidentiality of subject?	
12. **Total Budget (Approx. in Rs.)** Who will bear the cost of investigation / implants drugs / contrasts?	1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies (Name)_____
13. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ *Certified that Hindi version is a true translation of English version*
14. **Participant Informed Consent Form** *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ *Certified that Hindi version is a true translation of English version*
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief	1. _____ ☐ Yes ☐ No 2. _____ ☐ Yes ☐ No 3. _____ ☐ Yes ☐ No 4. _____ ☐ Yes ☐ No
16. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no)* *(Please enclose a separate certificate to this effect).*
17.Attached documents (If any)	17.1 Covering letter, through proper channel. 17.2 Copy of the detailed protocol is mandatory. 17.3 Brief CV of Investigators (including No. of projects with Principal Investigator) 17.4 Investigator's Brochure 17.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines 17.6 In case of multicentric study, IEC clearance of other centres must be provided 17.7 Definite undertaking as to who will bear the expenditure of injury related to the project 17.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) 17.9 Permission as mentioned in column 5.9 17.10 Certificate/undertaking as mentioned in column 16 17.11 Investigator should provide undertaking what they will do with the leftover sample tissue.

	17.12 Others
18. In case of clinical trials CTRI status	

PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant Information Sheet addressed to the patient or participant or parent/guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in a simple **understandable layman's language** in **English and Hindi**, which can be understood by them:

i) Title of the Study/Project

ii) Aims and methods of the research.

iii) Expected duration of the subject participation.

iv) The benefits to be expected from the research to the subject or to others.

v) Any risk to the subject associated with the study.

vi) Maintenance of confidentiality of records.

vii) Provision of free treatment for research related injury.

viii) Compensation of subjects for disability or death resulting from such injury.

ix) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

x) Amount of blood sample in quantity, in Tea Spoon Full, to be taken should be mentioned.

xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned.

xii) Telephone number/contact number of Principal Investigator and Co investigator at the top of each page.

xiii) In case of drug trials:

a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned

b) Initial Bio equivalent study of the drug / references should be provided

xiv) Self-certification should be given that translation to vernacular is accurate.

PARTICIPANT INFORMED CONSENT FORM (PICF)

(English)

Protocol / Study number :_____

Participant identification number for this trial: _____

Title of project:_____

Name of Principal Investigator: Tel.No(s).

The contents of the information sheet dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from MIMSR, Latur. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signatures / Left Thumb Impression) Place:

Name of the Participant: _____
Son / Daughter / Spouse of: _____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator Date:
Place:

1) Witness – 1

Signatures
Name:
Address:

2) Witness – 2

Signatures
Name:
Address:

NB: Three copies should be made, for (1) Patient, (2) Researcher, (2) Institution
(Investigators are advised to prepare the translation in simple understandable Marathi / Hindi on their own.)

Six monthly progress of Project

Institute Ethics Committee Reference No._____

Study title:_____

Name of the Principal Investigator_____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from _____to _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____

Date:_____

PROGRESS REPORT (Annual)/FINAL REPORT

1. Project/Trial Code Number

2. Title of the drug/multicentric trial

3. Principal Investigator (Name & Department)

4. Sponsor

5. Contract Research Organization (CRO) if any

6. Date of sanction by IEC

7. Date of start

8. Objectives of the study

9. Progress report as per objectives (attach separate sheet)

10. Serious Adverse Events if any with details (in summary form)

11. Protocol deviation if any with reasons/justifications

12. Report/publications/conference presentation

13. Awards/recognition

Date: (Signature of Principal Investigator)

(Signature of Head of the Department)

FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR BY THE MEMBER SECRETARY, INSTITUTIONAL ETHICS COMMITTEE

Dated:

To,

Prof. /Dr. _____

_____

Dear Prof. /Dr. _____

The Institutional Ethics Committee in its meeting held on _____, has reviewed and discussed your application to conduct the clinical trial/project entitled

“_____

_____”sponsored by

_____Code no._____

The following documents were reviewed:

a. Trial Protocol (including protocol amendments)/project, dated ____Version no (s).

b. Investigator’s Brochure, dated _____, Version no. _____

c. Patient Information Sheet and Informed Consent Form (including updates if any) in Marathi, Hindi, English and/or vernacular language.

d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.

e. Current CV of investigator from outside MIMSR, Latur.

f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.

g. Investigator’s Agreement with the Sponsor.

h. Investigator’s Undertaking.

i. Ethics Committee Proforma.

j. DCGI approval letter/submission letter.

k. Case Report Form

l. Any other/additional documents

Decision of Committee:

Institutional Ethics Committee

Member Secretary

GUIDELINES FOR PATIENT INFORMATION SHEET

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. Study Title

Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

2. Invitation Paragraph

You should explain that the patient is being asked to take part in a research/trial study. The following is an example:

"You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The background and aim of the study should be given here

4. Why have I been chosen?

You should explain how and why the patient was chosen and how many other patients will be studied.

5. Do I have to take part?

You should explain that taking part in the research/trial is entirely voluntary. You could use the following paragraph:-

"It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. What will happen to me if I take part?

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use – the following simple definitions may help:-

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual – i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither will you not your doctor know in which treatment group you are. (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

Placebo: A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research/trial the patient should be told what other treatment options are available.

10. What are the side effects of taking part?

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand

(e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

“It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study; neither should woman who plans to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of fetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

"We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better".

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You should also explain to them what treatment will be available instead.

Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

"If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The answer should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

19. Who has reviewed the study?

You may wish to mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

20. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study.

(Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers)

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.