Criteria III

Research, Innovations And Extension

(2024-25)

3.3 – Research Publications and Awards

3.3.1- Institutional Code of Ethics

(2024-25)

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STANDARD OPERATING PROCEDURES (SOP)

MKSSSBTINE-IEC (Institutional Ethical Committee)

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MKSSSBTINE-IEC (Institutional Ethical Committee) 2020-2021

Objectives of the standard Operating Procedures for Maharshi Karve Stree Shikshan Samstha's Smt. Bakul Tambat Institute of Nursing Education- Institutional Ethical Committee (MKSSSBTINE-IEC):

The Standard Operating Procedures (which shall be referred to as SOPs henceforth in this document) main aim is

- To define the procedures that the Maharshi Karve Stree Shikshan Samtha's Smt. Bakul Tambat Institute of Nursing Education- Ethic Committee (MKSSSBTINE-EC) shall follow to ensure quality, consistency and transparency in the ethical reviews processes and provide approval of research proposals base on the principles of respect for person, justice, beneficence.
- MKSSSBTINE-EC shall monitor the ongoing research at Maharshi Karve Stree Shikshan Samtha's Smt. Bakul Tambat Institute of Nursing Education (MKSSSBTINE), Pune.

The SOPs are base on handbook of National ethical guidelines for Biomedical and health research involving human participants by ICMR publish in the year 2017, 2018, 2019 and 2020.

1. Role of MKSSSBTINE-EC

- The MKSSSBTINE-EC shall review and monitor all types of research proposals conducted in MKSSSBTINE, Pune involving human participants with a view to look after the rights, self-respect, safety and welfare/ well being of all actual and potential research participants and to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner.
- The MKSSSBTINE-EC shall reviews researches application of all biomedical, social and behavioural science research for health conducted involving human participants and data.
- The MKSSSBTINE-EC shall ensure and review the research purposes that are conducted, for the betterment of others human beings who are participating in health research that respect the dignity and well being of participant.

- The MKSSSBTINE-EC shall evaluate all stages of the research, such as design, conduct and reporting of the results thereof.
- The MKSSSBTINE-EC shall take care that the principles of research ethics during the research process reviews viz autonomy, beneficence, non-maleficence, and justice including principles of essentiality, voluntariness, non-exploitation, social responsibility, confidentiality, risk minimization, professional competence, maximization of benefit, institutional arrangements, transparency and accountability, totality of responsibility and environmental protection.
- The MKSSSBTINE-EC shall assesses and analyse the benefit-risk assessment where attempts to maximize the benefits of research outcome and evaluate plans to minimize the risk and discomforts, and shall decide the merit of research before approval.
- The MKSSSBTINE-EC shall consider all aspects of informed consent process, review and approve before enrolment of participants, in which informed consent shall include relevant information about research to potential participants, ensuring the information is comprehended by them and assuring voluntariness of participation. In some cases, verbal/oral consent/waiver of consent/re-consent may be obtained under certain conditions after due consideration and approval.
- The MKSSSBTINE-EC shall ensure that researcher safeguard the privacy and confidentiality of the participants and the community.
- The MKSSSBTINE-EC shall ensure equitably distribution of benefit sharing in all types of researches in the participants from various ethnic backgrounds and avoid social, racial and ethnic inequality.
- The MKSSSBTINE-EC shall review before the start of the any research study. After appropriate process and clearance of the research, the EC shall be continuing with monitoring the research process in all phases of research until the end or termination of research. The researcher shall one submit a research study progress report annually for the EC to monitor.
- The MKSSSBTINE-EC shall approve the research proceeding after submission of first report for up to 2 years. The principle investigator/researcher shall submit his/her report 2 months prior to completion of approval duration of research study. If the PI fails to do so, he/she shall provide a written explanation to MKSSSBTINE-EC Chairman who will have the authority to give approval for extension of research duration for next year.

- The MKSSSBTINE-EC member may conduct site visit as case arise for monitoring purposes at the discretion of the Ethic committee decisions. The committee shall ensure compliance of all rules and regulation set by committee in SOP, applicable guideline given by government authority time to time.
- The MKSSSBTINE-EC shall be responsible for acting in the full interest of the research participants and society, considering the researcher interest and need into account.
- The MKSSSBTINE-EC shall make an effort to share or made it accessible of post research benefits to the individual participant, community. The committee shall make efforts to communicate the findings of the research study to the individuals/communities wherever relevant or facilitate availability of intervention benefits with the participants, including those in the control group.
- The MKSSSBTINE-EC shall ensure responsible conduct of research by maintaining high standard and upholding the fundamental value of research which shall include; policies; planning and conducting research; reviewing and reporting research; and responsible authorship and publication. EC shall be sensitive to the society need and review of impact of health research in the community. EC shall policy for protection of participant in place in experimentation. EC shall have planned to address the Conflict of Interest (COI) issues in place for identifying, mitigating, and managing COIs.

2. Composition of the MKSSSBTINE-EC as per ICMR guidelines:

- The MKSSSBTINE-EC shall be multi-disciplinary and multi-sectoral with adequate representation of age and gender.
- The MKSSSBTINE-EC shall have 50% of the members from non-affiliated or from outside the institution.
- The MKSSSBTINE-EC board shall consist of 7 to 12 members.
- The MKSSSBTINE-EC Chairperson of the board shall be from outside the institution i.e. MKSSSBTINE, Pune.
- The MKSSSBTINE-EC member secretary of the board shall be from the institution i.e. MKSSSBTINE, Pune and shall coordinate all the committee activities.
- The MKSSSBTINE-EC shall have minimum of 5 members as quorum of requirement for EC meetings.

- The MKSSSBTINE-EC shall have basic medical/non medical scientist, clinician, legal expert, biostatistician, sociologist and subject speciality expert of the field representating diverse point of view in board.
- The MKSSSBTINE -EC shall maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician/ Child Health Nurse for research in children, a cardiologist/ CVT nurse for research on heart disorders, etc. They shall be invited to attend the meeting to give an expert opinion on a specific proposal but shall not have decision making power/voting rights for approval of research proposal.

As per ICMR guidelines, the composition of the MKSSSBTINE-EC shall thus be as follows:

- Chairperson from outside the institute, MKSSSBTINE, Pune.
- Member Secretary from the institute, MKSSSBTINE, Pune.
- 4 members from different specialities/discipline as specified below:
    - Health scientist/ researchers from nursing or bio-medicine.
    - Clinician/ health practitioners from nursing or bio-medicine.
    - Legal expert.
    - Social scientist/ ethicist/ philosopher.
    - Lay person as representative of the community.

Criteria for selection of ethical committee members:

MKSSSBTINE-EC members shall be selected as per their professional and personal capacity to contribute in the committee base on their interest, ethical and scientific knowledge and expertise in their respective field.

Conflict of interest shall be avoided and disclosure of COI in forefront when appointment is issues, but where unavoidable, transparency will be in place in such conflict of interests.

New member will be added as per committee board composition requirement and new member personal capacity and provided that the potential member fulfils the membership as define in this SOP.

The qualities of member sought:

- Interest in ethical research
- Educated
- Willing to spend time in creating ethical research culture.

- Commitment and effort to contribute
- Experience
- Integrity and good decision making.

3. Authority under which the MKSSSBTINE-EC is constituted:

The head of the institute, Principal, MKSSSBTINE, Pune

4. Offices:

The MKSSSBTINE-EC will have the following office bearer to review the research proposals:

- **Chairperson:** The chairperson shall be the head and conduct all the ethical committee meeting. In absence of the chairperson, an alternative chairperson shall be elected by the members present in the meeting, who shall conduct the meeting on behalf of the absentee.

- **Member Secretary:** The member secretary is responsible for organizing the meetings, maintaining the records and communicating with all those concerned. She/he shall maintain minutes meeting pass by the chairperson. She/ he shall inform decision notice made by ethic committee to the researcher(s) whose project had been reviewed after confirming and getting approval from Chairperson within 15 days of committee meeting.

- Member secretary will maintained all the MKSSSBTINE-EC documents and data record for a period of not less than five years from the date of termination of the project.

5. Administrative Staff of MKSSSBTINE-EC:

- Administrative staff including an accountant and junior clerk will be appointed along with attendant for the smooth running of the office and meeting as required by EC.
- Account shall be responsible for any accounts related to expenditure of running office.
- Junior clerk shall perform her responsibility as per direction and requirement of the EC.

- Attendant shall facilitate in various duties assigned to them from time to time as per EC direction.
- Duties of the administrative staffs:
- The administrative staff will report to Chairperson and member secretary of EC in the MKSSSBTINE, Pune.
- Office timing will be as per MKSSSBTINE, Pune rules and regulations.
- The administrative will be having sick leave/CL/ EL as per MKSSSBTINE, Pune rules and regulations.
- Facilitate and arrange in correspondence with EC members, subject expert, from outside agencies.
- Arrange correspondence with the researcher/ investigators
- Keeping records, inward, outward registry related to the correspondence.
- Answering queries of the investigators
- Filing and keeping records of study related documents.
- Storing of archived records and maintaining the records.

6. Roles and responsibilities of MKSSSBTINE-EC members and terms of membership:

6.a. Roles and responsibilities of MKSSSBTINE-EC:

- The appointed MKSSSBTINE-EC members shall duly fulfil their role and responsibilities.
- Members shall be required to review the research proposal submitted in the committee as per their expertise and professional knowledge and suggest/opinion are put forth in the meeting by participating in the discussion during the meeting in professional manner.
- Members shall monitor any ongoing research process reviewed by the committee.
- Member shall commit to spend a minimum of 6 hours duration for two days in a year for the purpose of EC meeting for research review of researcher.
- All members are required to be thorough with SOP and protocol of EC.
- All members shall declare their disclosure of COI if any and excuse themselves if there is COI, from specific research review and related protocol and decision making.

- All the members shall attend the schedule meeting, if unable to do, they shall inform about the absentee with prior intimation at the earliest to the member secretary, so that substitution may be arrange if required.
- Members shall require attending at least one committee meeting in a year in person. There shall be provision for attending the meeting in video conference/online-conference medium as per situation permit. The document required for review shall be arranged priorly by sending through mail, scanning, faxing etc. In absentee of member, the quorum requirement shall be met by committee members present during the meeting.
- All the members shall be given research proposal material 2 days prior to the schedule meeting for review.

6.b. Terms of membership:

- The duration of the appointment of MKSSSBTINE-EC members shall be period of three years.
- At the end of the stipulated 3 years, as the case may be, the membership will be renew for another 3 years term, and reconstituted, new member shall replace present member who wish to retired or discontinue or need to be replaced.
- New member shall be mentor by senior member committee on running of the office and EC SOP and protocols.
- New membership shall be invited regularly to join MKSSSBTINE-EC meeting so that they are thorough with EC roles and responsibilities. New member shall be appointed as per their personal and professional experience capacities in the required field.

6.c. Resignation/Replacement procedure:

- A member shall be replaced in event of retirement, resignation, death or long-term non availability, inability to attend/ participate in at least one meeting in a year.
- A member shall be replaced if his/her actions are not according to roles and responsibilities led down by MKSSSBTINE-EC membership as judge by 2/3rd majority of the MKSSSBTINE-EC members appointed.

6. d. Confidentiality:

- All members required to maintain confidentiality of the meeting related discussion in form of writing or verbal information and they should not discuss any information to anyone except EC members. Confidentiality includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft.

- All personal copies of data and documents including emails, correspondence shall be treated as confidential material and should not be shared with outside agencies.
- All the members shall sign non-disclosure form at the time of joining of EC. The

6.e. Identifying, mitigating and managing COIs:

- Researcher shall submit documents to the EC as disclosure of COI and ownership or any funding received from sponsors (financial or non-financial) that may affect their research.
- EC shall monitor the research or check research results for accuracy and objectivity to avoid any conflict of interest.
- EC shall ensure that researcher are not having conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties by disclosing of COIs including sponsor (if any).
- All EC members shall disclose their own conflict of interest if any as reviewer in meeting.
- If any EC members have any COI, they must recused themselves from reviewing or decision making on that particular research protocols.

7. Quorum requirements:

- A minimum of 5 members are required to compose a quorum.
- All EC decisions should be ideally taken in meetings except in special circumstance requiring expedited reviews.

8. Independent Consultants:

MKSSSBTINE IEC may call subject experts as independent consultants who may provide special review of selected research protocol if need arises. MKSSSBTINE IEC experts may be related to specialize in the field like ethical and legal aspects, specifics disease (Cancer, HIV, mental disorders etc), novel diseases (COVID-19) or ethnic minorities. The independent consultants are required to give their valuable expert suggestion and contribution. But they will not take part in decision making process made by the members of MKSSSSBTINE-IEC.

9. Application procedures

a. **Who can apply:**

- Faculty members, Post graduate, Ph.D Nursing scholars of MKSSSBTINE, Pune

- Staffs and faculties members of Maharshi Karve Stree Shikshan Samstha's others institutes like Siddhivinayak Art, Commerce and Science, Centre of Skill development Department, Data Science Institute etc. who wish to do nursing and clinical researches.
- Independent researches affiliated to Non Government Organization, laboratories and organizations in the field of Humanity and allied health sciences.

b. Application detail:

- All research proposals should be submitted in prescribe application form, the details annexure attached and listed in the documentation point.
- All relevant documents should be enclosed with the application form.
- The application forms in the recommended prescribed format and duly signs by the Principal Investigator (PI) and co-investigator/collaborator along with all relevant documents should be electronically submitted to the MKSSSBINE IEC member of secretary at least 15 days before the date of MKSSSBINE IEC meeting commencement.
- The detail information about meeting like date, time, and venue will be intimated to the researcher, to be present, if necessary to offer clarification.
- For the external agencies, a prescribed fee of Rs. 5000/- to Rs.10000/- depending on grant amount or non-grant studies shall be remitted along with the application.
- The decision of the MKSSSBINE IEC shall be communicated in writing to the PI/ researcher.
- If any revision is to be made in the proposal, the revise document should be submitted electronically within a stipulated period of time as specified in the communication or before the next meeting.

c. Documentation

- The PI or researcher should submit the following documents:
- Name of the applicant with designation.
- Name of the institute /hospital/field area where research will be conducted.

- Approval of the Head of the Department /Institution.
- Protocol of proposed research.
- Ethical issues in the study and plans to address the issues.
- Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow up cards.etc.
- Informed consent processs, including patient information sheet and informed consent form in local language(s).
- For any drug/ device trial, all relevant pre-clinical trial data from others centre within the country, if available.
- Curriculum vitae of all the investigators with relevant publication if any
- Any regulatory clearance required.
- Source of funding and financial requirement for the research project.
- An agreement to report only Serious Adverse Events (SAE) to MKSSSBTINE IEC
- Statement of conflicts of interest, if any.
- Agreement to comply with the relevant national and applicable international guidelines.
- A statement describing any compensation for the study participants (including expenses and access to medical care) to be given to research participants: a description of the arrangements for indemnity, if applicable (in study-related injuries): a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g.: modified research protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
- Plans for publication of results- positive or negative- while maintaining the privacy and confidentiality of the study participants.
- Any other information relevant to the study.

10. Review procedures:

The MKSSSSBTINE-IEC should review every research proposal on human participants before the research is initiated and should ensure that a scientific evaluation has been completed before ethical review is taken up.

10.1. Conduct of reviews:

- The meeting of MKSSSSBTINE-IEC will be held on schedules intervals and additional meeting will be held as per situation arises.
- The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation like informed written consent process. Documentation, and the suitability and feasibility of the research protocol for ensuring privacy, confidentiality and the justice issues.
- The MKSSSSBTINE-IEC member-secretary shall allocates research proposal to 1 or 2 primary reviewers to prepare a detailed screening and evaluation for their completeness and after such evaluation, research proposals can then be discussed by all members of MKSSSSBTINE-IEC.
- Researcher/PI should make an oral presentation to MKSSSSBTINE-IEC and clarify any questions pose by members of MKSSSSBTINE-IEC.
- PI shall be given opportunity to clarify for rationality of study, its novel approaches, and offer clarification if needed.
- Independent experts/ consultants shall be invited to offer their suggestion, guidance, expert opinion on subject present if and when needed.
- Decisions of MKSSSSBTINE-IEC shall be taken by consensus after discussions.
- The discussion shall be recorded by member of secretary, and signed by members present at the meeting and Chairperson's will provide approval in writing.
- All members of MKSSSSBTINE-IEC including those who were not present at the meeting will be informed about the meeting proceeding and decision via official email.
- Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life

activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life. An investigator cannot decide that her/his protocol falls in the exempted category without approval from the IEC. All proposals will be scrutinised to decide under which of the following three categories it will be considered: 1. Exemption from review Proposals which present less than minimal risk fall under this category as may be seen in following situations: i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Exceptions: i. when research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm. ii. When interviews involve direct approach or access to private papers.

10.2 Element of review:

- Title of the study
- Objectives and research questions, hypothesis, need of the study.
- Scientific design and conduct of the study
- Examination of predictable risks/harms
- Examination of potential benefits
- Procedures of subject participants like inclusion, exclusion and withdrawal criteria.
- Management of research related injuries, AE and SAE
- Compensation provisions
- Patient information sheet and informed consent form in local language.
- Protection of privacy and provision of confidentiality.
- Involvement of the community and local areas.

- Plan for data analysis and reporting with safety and quality assurance plan reports
- Competence of PI, and supporting staff.
- Facilities and infrastructure of study sites

10.3 Expedited review

The research proposals presenting no more than minimal risk to research participants may be subjected to expedited review.

The Member- Secretary and the Chairperson of the MKSSSSBTINE-IEC or designated member of the Committee may do expedited review only if the protocols involve –

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).

2. Revised proposal previously approved through full review by the MKSSSSBTINE-IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

3. Research activities that involve only procedures listed in one or more of the following categories:

- Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation

- When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
- Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

b. Research on disaster management: A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

- Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
- Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
- Extra care must be taken to protect the privacy and confidentiality of participants and communities.
- Protection must be ensured so that only minimal additional risk is imposed.
- The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.
- All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
- Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

10.4. Full Review:

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members. While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

- From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;
- From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;
- From neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 - 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
- Prospective collection of biological specimens for research purposes by non-invasive means. For instance:
    - 1. skin appendages like hair and nail clippings in a non-disfiguring manner;
    - 2. dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
    - 3. Excreta and external secretions (including sweat);
    - 4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue; 5. placenta removed at delivery;

- 6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- 7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- 8. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through non-invasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance –

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow,
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

10.5. Review Process:

The method of review should be stated in the SOP whether the review should be done by all reviewers or by primary reviewer(s) in which case a brief summary of the project with informed consent and patient information sheet, advertisements or brochures, if any, should be circulated to all the other members. The ethical review should be done in formal meetings and EC should not take decisions through circulation of proposals. The committee should meet at regular intervals and should not keep a decision pending for more than 3 - 6 months, which may be defined in the SOP.

- PERIODIC REVIEW- the ongoing research may be reviewed at regular intervals of six months to one year as may be specified in the SOP of the ethics committee.
- CONTINUING REVIEW The IEC has the responsibility to continue reviewing approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if need be.
- INTERIM REVIEW Each IEC should decide the special circumstances and the mechanism when an interim review can be resorted to by a sub-committee instead of waiting for the scheduled time of the meeting like re-examination of a proposal already examined by the IEC or any other matter which should be brought to the attention of the IEC. However, decisions taken should be brought to the notice of the main committee.

11. Decision making procedure:

The IEC should be able to provide complete and adequate review of the research proposals submitted to them. It should meet periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones, review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate. The following points should be considered while doing so:

1. The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary should communicate the decision in writing to the PI.

2 .If a member has conflict-of-interest (COI) involving a project then s/he should submit this in writing to the chairperson before the review meeting, and it should also be recorded in the minutes.,

3. If one of the members has her/his own proposal for review or has any COI then s/he should withdraw from the IEC while the project is being discussed

4. A negative decision should always be supported by clearly defined reason

5. An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio. 6. The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

7. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.

8. The following circumstances require the matter to be brought to the attention of IEC:

a. any amendment to the protocol from the originally approved protocol with proper justification;

b. serious and unexpected adverse events and remedial steps taken to tackle them;

c. any new information that may influence the conduct of the study.

9. If necessary, the applicant/investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or interest groups can be invited during deliberations to offer their viewpoint.

10. Subject experts may be invited to offer their views, but should not take part in the decision making process. However, her / his opinion must be recorded.

11. Meetings shall be minuted which should be approved and signed by the Chairperson/ alternate Chairperson/ designated member of the committee.

12. Communication within the MKSSS BTINE IEC

- Decision(s) taken by MKSSSSBTINE-IEC shall be duly communicated by the members of Secretary in writing to all the members of the MKSSSSBTINE-IEC and those concerned directly/ indirectly with such decisions.
- Suggestions for modifications in the proposal/ protocol, if any, should be duly communicated to the researcher by the MKSSSSBTINE-IEC.
- Reason(s) for rejection shall be informed to the researchers.

- The schedule/ plan of ongoing review by the MKSSSSBTINE-IEC shall be communicated to the PI.

13. Appeal procedures: This procedure is:

- Where the MKSSSBTINE IEC has rejected an application for ethics approval (for reasons other than the application being incomplete) and the researcher applicant wishes to appeal.
- Where the MKSSSBTINE-IEC has approved an application for ethics approval subject to some changes being made and the researcher disagrees with the proposed changes. In this case, before making a formal appeal, the researcher should initially confer with the chairperson for clarification of the reasoning of the EC.

After this consultation, if the researcher is not satisfied then she /he can make a formal appeal as outline below.

- If the researches wish to appeal a decision made as a part of the approval process, he/she must notify the chairperson of the MKSSSBTINE-EC through the member's secretary. The appeal should be in writing and must be sent via post or email within 14 days of being notified of that decision.
- The chairperson can appoint a committee independent of the MKSSSBTINE-EC who will then review the application and give recommendations to the EC.
- The membership of the panel shall be at the discretion of the MKSSSBTINE-EC chairperson.
- Once the panel has reached its decision, the panel chairperson can give the recommendations of the committee to the MKSSSBTINE-EC and based on the recommendations the MKSSSBTINE-EC can make an amended decision his decision cannot be appealed against, using the procedure described above.

14. Follow up procedure:

- All ongoing projects that have been given ethical approval have to submit their annual reports to the MKSSSBTINE-EC at 12 months after approval was granted. These would then be tabled at the next MKSSSBTINE-EC meeting.
- Final report should be submitted at the completion of the study.

- All SAEs (Severe adverse events) and the action interventions under taken for the research should be intimated to the MKSSSBTINE-EC chairperson and / or member secretary, ideally immediately, and within 72 hours of occurrence. In the event of non-availability of the chairperson and /or the member secretary, the same shall be notified to other members of the EC, which shall be notified to the chairperson and /or the member secretary) not exceeding one week after the reporting o the SAE by the researcher /research team member. If case delay in reporting the SAE by the researcher /research team member occurs, prompt and approximate action against the researcher shall be initiated by the EC. It can be decided to suspend /terminate the project as decided by the EC. The decision of the MKSSSBTINE shall be final.
- All protocol deviations, if any should be promptly informed with adequate justifications for the same to the MKSSSBTINE-EC chairperson. The chairperson will then decide if the fresh approval is indicated. Any major deviations (such as change in design, target sample, inclusion of new intervention component) will require resubmission for fresh approval.
- Minor amendment (s) to the protocol (such as increasing or decreasing number of people to be interviewed) Do not need fresh approval from the MKSSSBTINE-EC the chairperson and secretary can give necessary permission for inclusion of the change to the original protocol or such information should be recorded and communicated to the MKSSSBTINE-EC through the annual reports.
- Premature termination/suspension of the study should be duly notified with approximate and adequate justification along with the summery of data obtained so far.
- Any change of the investigators /site(s)/sponsor (s)/funding (s) should be duly informed to the MKSSSBTINE-EC within 1 week failing which approximate and prompt action against the investigator shall be initiated by the EC.

15. Record keeping and archiving

The MKSSSBTINE-EC shall be required to maintain the following records for a period of at least 5 years (or as the quorum deems it necessary). The member secretary shall be responsible for the same.

- Curriculum vitae (CV) of all members of EC

- Copy all of study protocol with enclosed documents, progress reports, reports on SAEs protocol deviations and any further documents/reports that the MKSSS BTINE-EC may require the researcher to provide.
- Each application will be provided with a unique ID number which will maintained for all documents related to that particular project/application. All documents related to a particular project will be saved in hard as well as soft copy in a designated folder. The folder will be password protected and accessible only to the MKSSS BTINE members. All hard copies will be kept under lock and key.
- Minutes of all meetings duly signed by the chairperson of the EC. The minutes of meeting shall be noted by the personal secretary (PS) and consequently typed. It is the duty of the member secretary to the duly maintained the typed minutes prepared by the PS.
- A copy of all exciting relevant national and international guidelines/updates /amendments on research ethics and laws amendments.
- A copy of correspondence with members, researchers and other regulatory bodies.
- Annual and final reports of all the approved projects.
- All publications related to a particular proposal should be submitted to the MKSSS BTINE -EC for record purposes. Ethics approval should be acknowledged in all research manuscripts arising from the approved study.

16. Updating MKSSBTINE IEC members

Any relevant updates /guidelines in the processes of the MKSSS BTINE-EC shall be brought to the immediate attention of the members. Member shall be encouraged to attend national and international training programmes in research ethics for maintaining quality in ethical review by being updated with latest development in this milieu.

17. Remuneration for IEC members

All members shall be paid remuneration per meeting as well as the cost of travel for participation in the meetings as per the university rules.

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Research publication process at BTINE

MKSSS, Smt. Bakul Tambat Institute of Nursing Education conduct researches as a part of curriculum. Our undergraduate and postgraduate students perform researches under the guidance of Principal and faculties. We conduct individual as well as group projects. Since result of every research is valuable, it should reach to all research fraternity. This is possible only when it is published in national or international journal. This also helps the researchers in the same field.

Keeping this in mind, we are maintaining details of publication process and list of subject journals. We maintain separate file of author guidelines of publishing.
We are also providing links of authentic database like Scopus WOS UGC care list etc. for easy selection of journals.

We have made a basic document on Research FAQS for Faculty including following details.

Research FAQs

What is research article?

A research article reports on a specific, **original** research project or experiment. When a scientist comes up with a research question, forms hypotheses, performs experiments, and analyses the results in order to answer the original research question, they write a **research article** describing this whole process to other scientists.

What are types of research articles?

Original research - These are detailed studies reporting original research and are classified as primary literature.

Review article - It provide a critical and constructive analysis of existing published literature in a field, through summary, analysis, and comparison, often identifying specific gaps or problems and providing recommendations for future research.[1,6] These are considered as secondary literature since they generally do not present new data from the author's

experimental work. Review articles can be of three types, broadly speaking: literature reviews, systematic reviews, and meta-analyses.

Clinical case study - Clinical case studies present the details of real patient cases from medical or clinical practice. The cases presented are usually those that contribute significantly to the existing knowledge on the field. The study is expected to discuss the signs, symptoms, diagnosis, and treatment of a disease.[1,5] These are considered primary literature and usually have a word count similar to that of an original article. Clinical case studies require a lot of practical experience and may not be a suitable publication format for early career researchers.[5]

Perspective, opinion, and commentary - Perspective pieces are scholarly reviews of fundamental concepts or prevalent ideas in a field. These are usually essays that present a personal point of view critiquing widespread notions pertaining to a field.[1-3] A perspective piece can be a review of a single concept or a few related concepts. These are considered as secondary literature and are usually short articles, around 2000 words.[2]

Short Communications - Original research and /or clinical studies that do not require a full paper, but are completed studies, may be submitted as Short Communications. These papers may detail a smaller number of observations or may include a smaller number of patients.

Case Report - Short articles of a clinical nature which illuminate an underlying principle of a disease state, its diagnosis, or its therapy

What is common article pattern?

Title - Make your title specific enough to describe the contents of the paper, but not so technical that only specialists will understand. The title should be appropriate for the intended audience.

Authors - The person who did the work and wrote the paper is generally listed as the first author of a research paper.

Abstract - An abstract, or summary, is published together with a research article, giving the reader a "preview" of what's to come. Your abstract should be one paragraph, which summarizes the purpose, methods, results and conclusions of the paper.

Introduction

A competent introduction should include at least four key concepts: 1) significance of the topic, 2) the information gap in the available literature associated with the topic, 3) a literature review in support of the key questions, 4) subsequently developed purposes/objectives and hypotheses.

Materials and methods

The methods section should clearly describe the specific design of the study and provide clear and concise description of the procedures that were performed. The purpose of sufficient detail in the methods section is so that an appropriately trained person would be able to replicate your experiments. The methods section should include a clear statement that the researchers have obtained approval from an appropriate institutional review board.

Results /Discussion

In most journals the results section is separate from the discussion section. It is important that you clearly distinguish your results from your discussion. The results section should describe the results only. The discussion section should put those results into a broader context. Report your results neutrally, as you "found them". Again, be thoughtful about content and structure. Think carefully about where content is placed in the overall structure of your paper. It is not appropriate to bring up additional results, not discussed in the results section, in the discussion. All results must first be described/presented and then discussed. Thus, the discussion should not simply be a repeat of the results section.

Tables and graphs

If you present your data in a table or graph, include a title describing what's in the table. For graphs, you should also label the x and y axes.

Conclusion

Finish with a concise, 3-5 sentence conclusion paragraph. This is not just a restatement of your results, rather is comprised of some final, summative statements that reflect the flow and outcomes of the entire paper. Do not include speculative statements or additional material; however, based upon your findings a statement about potential changes in clinical practice or future research opportunities can be provided here

Acknowledgement

This section is optional. You can thank those who either helped with the experiments, or made other important contributions

References

There are several possible ways to organize this section. Example APA style Vancouver style etc. This should be done according to guidelines of specific journal.

What is impact factor?

The impact factor (IF) or journal impact factor (JIF) of an academic journal is a scientometric index that reflects the yearly average number of citations that articles published in the last two years in a given journal received. It measures the quality of journal.

What is h index?

The *h*-index is an author-level metric that measures both the productivity and citation impact of the publications of a scientist or scholar. The index is based on the set of the scientist's most cited papers and the number of citations that they have received in other publications.

What is UGC care list?

To match global standards of high quality research, in all academic disciplines under its purview, the University Grants Commission (UGC) aspires to stimulate and empower the Indian academia through its "Quality Mandate.UGC-CARE has taken the responsibility of preparing the "UGC-CARE Reference List of Quality Journals" (UGC-CARE List).A list of Indian journals, especially from disciplines of Arts, Humanities, Languages, Culture and Indian Knowledge Systems is being prepared and updated quarterly (UGC-CARE Group I).The UGC-CARE List includes journals from all disciplines indexed in globally accepted databases, such as indexed in Scopus (Source list) or Web of Science (Arts and Humanities Citation Index Source Publication, Science Citation Index Expanded Source Publication, Social Science Citation Index Source Publication). These journals are to be considered for all academic purposes. Journals indexed in Scopus and / or Web of Science are part of UGC-CARE List Group II.

What is Scopus?

Scopus is Elsevier's abstract and citation database launched in 2004. Scopus covers nearly 36,377 titles (22,794 active titles and 13,583 inactive titles) from approximately 11,678 publishers, of which 34,346 are peer-reviewed journals in top-level subject fields: life sciences, social sciences, physical sciences and health sciences. It covers three types of sources: book series, journals, and trade journals. All journals covered in the Scopus database, regardless of who they are published under, are reviewed each year to ensure high quality standards are maintained. Searches in Scopus also incorporate searches of patent databases.[11] Scopus gives four types of quality measure for each title; those are *h*-Index, Cite Score, SJR (SC Imago) and SNIP (Source Normalized Impact per Paper).

What is web of science?

Web of Science is a platform consisting of several literature search databases designed to support scientific and scholarly research **Web of Science Core Collection** is our premier resource on the platform and includes over 21,000 peer-reviewed, high-quality scholarly journals published worldwide (including Open Access journals); over 205,000 conference proceedings; and over 104,000 editorially selected books.

How to publish in ugc care list 1 journal?

Create an account **at https://ugccare.unipune.ac.in/Apps1/User/lr/login**

Here you can search journals of your interest in group 1.

Most of the Indian journals are coming under wolter and Kluwer publication. They have their own system login to it and then submit article electronically.

www.journalonweb.com.

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List of Recommended Journals in Nursing

SN	Title	Database
1	Nursing practice today	DOAJ
2	International journal of advance medicine and health research	DOAJ
3	Journal of family and community medicine	DOAJ
4	Journal of Krishna institute of medical science university	DOAJ
5	Archives of Medicine and Health Sciences	DOAJ
6	Central European Journal of Nursing and Midwifery	DOAJ
7	Journal of Family Nursing	Sage Publication
8	Journal of Research in Nursing	Sage Publication
9	Journal of School Nursing	Sage Publication
10	Journal of Transcultural Nursing	Sage Publication
11	Nursing Ethics	Sage Publication
12	Nursing Science Quarterly	Sage Publication
13	Western Journal of Nursing Research	Sage Publication
14	South Asia research	Sage Publication
15	Indian Journal of Continuing Nursing Education	UGC Care List
16	Indian Journal of Psychiatric Nursing	UGC Care List
17	Medical Journal of Dr. D. Y. Patil Vidyapeeth	UGC Care List
18	International Journal of Advanced Medical and Health Research	UGC Care List
19	Journal of Mental Health and Human Behaviour	UGC Care List
20	Indian journal of medical ethics	Scopus
21	Indian Journal of Medical Microbiology	Scopus
22	Indian Journal of Medical Research	Scopus
23	Indian Journal of Medical Sciences	Scopus
24	Indian Journal of Medical Specialities	Scopus
25	Indian Journal of Community Medicine	Scopus

SN	Title	Database
26	Indian Journal of Psychiatry	Scopus
27	Indian Journal of Psychological Medicine	Scopus
28	The journal of obstetrics and gynecology of India	Scopus
29	Indian Journal of Psychological Medicine	Scopus
30	Indian journal of public health	Scopus
31	Indian Heart Journal	Scopus
32	Iranian Journal of Nursing and Midwifery Research UGC care	Scopus
33	Asia-Pacific Journal of Oncology Nursing	Medknow
34	Egyptian Nursing Journal	Medknow
35	Indian Journal of Continuing Nursing Education	Medknow
36	Indian Journal of Psychiatric Nursing	Medknow
37	Iranian Journal of Nursing and Midwifery Research	Medknow
38	Journal of Integrative Nursing	Medknow
39	Journal of Nursing and Midwifery Sciences	Medknow
40	Nursing and Midwifery Studies	Medknow
41	JOURNAL OF RESEARCH IN MEDICAL SCIENCES	Web of Science
42	NATIONAL MEDICAL JOURNAL OF INDIA	Web of Science
43	INDIAN PEDIATRICS	Web of Science

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