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RESEARCH ETHICAL GUIDELINES

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MKSSS,SNCON-IEC(Institutional Ethical Committee)**

Objectives of the Institutional Ethical Committee for Maharshi Karve Stree Shikshan Samstha's , Sitabai Nargundkar college of Nursing for women(MKSSS,SNCON-IEC):

Aims and Objective

- To expound the procedures that the Maharshi Karve Stree Shikshan Samstha's **Sitabai Nargundkar college of Nursing for women- Ethical Committee (MKSSS,SNCON-IEC)** shall follow to ensure standardized , consistent and transparency in the ethical reviews processes and will provide approval of research proposals base on the principles of respect , justice, beneficence.
- To Create an enabling environment and to contribute the effective functioning of MKSSS, SNCON research Ethical committee.
- MKSSS, SNCON will formulate and publish ethical guidelines that are simple, understandable and acceptable.

The Booklet is based on handbook of National ethical guidelines for Biomedical and health research involving human participants by ICMR publish in the year 2017 to 2020.

1. NORMS AND GUIDELINES FOR RESEARCH ETHICS AND PUBLICATION AS PER ICMR GUIDELINES

- The MKSSS,SNCON-IEC shall monitor and evaluate all types of research proposals involving human participants with a view of conserving their rights, self-respect, safety and welfare well being of all actual and capable research participants.
- Research committee shall work on effective functioning on MKSSS,SNCON ethical committee , for potent and qualitative ethical review mechanism for health and biomedical research in the institution.
- MKSSS,SNCON shall review and approve types of research to those involving safeguard, rights ,safety and well being of actual and potential researchers.
- MKSSS,SNCON ethical committee shall review the research statement before the onset of research process ,monitor it ,during and after the completion of the research study .
- The MKSSS,SNCON-IEC shall take care of all the principles of research ethics during the research activities viz autonomy, beneficence, non-maleficence, and justice including principles of essentiality, voluntariness, non exploitation, social responsibility, confidential risk minimization, professional competence ,maximization of benefit, institutional arrangements, transparency and accountability, totality of responsibility environment protection and provision of appropriate comprehension wherever and whenever required.
- The MKSSS,SNCON-IEC shall consider 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 MKSSS,SNCON-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 the participants, ensuring the information is well determined to them and assuring their voluntarily participation. In some cases, verbal/oral consent/wave of consent/re-consent is obtained by under certain conditions after due consideration and approval.
- The MKSSS,SNCON-EC shall ensure that researcher safeguards the privacy and confidentiality of the participants in the community.

- The MKSSS,SNCON-EC shall ensure equitable distribution of benefit sharing in all types of research studies for participants from various ethnic backgrounds and ,racial and ethnic inequality..
- The MKSSS,SNCON-EC member may research setting visit site as in case monitoring purposes at the discretion of the Ethic committee decisions. The member shall ensure adherence of all rules and regulation set by ethical committee .
- The MKSSS,SNCON-IEC shall be responsible for acting in the need and the interest of the research participants and society.
- The MKSSS,SNCON-IEC shall make an attempt to share or make it accessible for post research benefits to the participant ,individual and the community. The committee shall make an efforts to communicate the findings of the research study to the individuals/communities wherever relevant and will facilitate availability of intervention benefits with the participants, including those in the control group.
- The MKSSS,SNCON-IEC shall ensure responsible conduct of research by maintaining high standard and upholding the fundamental value of research which will include ;
 1. policies; planning and conducting research;
 2. reviewing and reporting of the research study ;
 3. authorship and publication of the research conducted.

EC shall be sensitive to the society needs and will have review of impact of health research in the community. EC shall have policy for protection of researcher in place of experimentation.EC have planned to address the deal with Conflict of Interest (COI) issues in place of identifying, mitigating, and managing COIs

Criteria for selection of ethical committee members:

MKSSS, SNCON-EC members shall be selected as per their professional and personal capacity and growth to contribute in the committee on the bases on their interest, knowledge of scientific ethics and expertise in their respective field.

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

New member will be added as per committee board requirement , new member personal capacity and provided that the potential member fulfil the membership in the committee

The qualification of the member required :

- Interest in ethical research
- Educated
- Interested in spending time in creating ethical research culture.
- Commitment and effort to contribute in research process
- Experienced and has ethical knowledge .
- Integrity and good decision making.

1. Authority under which the MKSSS,SNCON-EC is constituted:

The head of the institute, Principal, MKSSS,SNCON-EC,Nagpur

2. Offices bearer:

The MKSSS,SNCON-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 who are concerned. She/he shall maintain minutes meeting passed 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 MKSSS,SNCON-EC documents and data record for a period of not less than five years from the date of termination of the project.

Review procedures:

The MKSSSS,SNCON-EC 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.

1. Conduct of reviews:

- The meeting of MKSSSS, SNCON-EC will be held on scheduled intervals and additional meeting will be held as per situations and circumstances.
- 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 maintaining privacy, assurance of confidentiality and the justice issues.
- The MKSSSS,SNCON-EC member-secretary then assigns research proposal to 1 or 2 primary reviewers to prepare a detailed screened evaluation report for their completeness and after such evaluation, research proposal scan it is then discussed by all members of MKSSSS,SNCON-EC.
- Researcher/PI should make an oral presentation to MKSSSS,SNCON-EC and clarify any questions presented by member of MKSSSS,SNCON-EC.
- Researcher shall be given opportunity to clarify for rationality of study, its novel approaches, and offer clarification if required .
- Independent experts/ consultants shall be invited to offer their suggestion, guidance, expert opinion on subject present if and when needed.
- Decisions of MKSSSS,SNCON- EC 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 MKSSSS,SNCON-EC including those who were not present at the meeting will be informed about the meeting proceeding and decision.

- Minimal risk would be defined as one which may be anticipated as harmony 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 everyday life. An investigator cannot decide that her/his protocol falls in the exempted category without approval from the EC. All proposals will be scrutinized 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:
Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or class room management methods.
2. 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 ui798 .ii.When interviews involve direct approach or access to private papers.

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 with drawl criteria.

- Management of research related injuries,
- 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 the study sites.

3. Expedited review

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

The Member-Secretary and the Chairperson of the MKSSS,SNCON-EC 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
2. Revised proposal previously approved through full review by the MKSSS,SNCON-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.

Research 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.

a. **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 is also sometimes 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 research:

- Research plan to be conducted after a disaster should be essential in culture sensitive and specific in nature with possible application in future disaster situations.
- Disaster affected community participation before and during the research is essential and ethical considerations must be kept in focus.
- Extra care must be taken to protect the privacy and confidentiality of participants and their communities in every senses.
- Their search undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster-affected population and a prior agreement should be made 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.

Institutional policy on plagiarism

Plagiarism is the practice of copy, paste or reproducing other persons work or ideas without acknowledging the source and taking credit as it one's own. The dictionary meaning of plagiarism as Wrongful appropriation close imitation and publication of another authors language thoughts, ideas or expressions and representation of them as owns original work nevertheless the act is unlawful, unethical and even criminal

Plagiarism is a serious academic misconduct and violation of code of conduct in educational environment. It affects the quality, integrity, respect and fairness. Authors committing plagiarism without acknowledgment of the source are actually doing theft of intellectual property and should misconduct to avoid plagiarism. The authors must cite or give credit to others work whether published/ unpublished, written or oral presentation.

Sitabai Nargundkar college of nursing for women is committed to maintain the standard and originality of research work which is reviewed through review committee established at institutional level our library is equipped with quality journals, e-journals which help to provide a plat form for quality research

Maharshi Karve Stree Shikshan Samstha's, Sitabai Nargundkar College of Nursing for Women. plagiarism policy in the purview of UGC and Maharashtra University of Health Sciences norm are as follows

- The MKSSS,SNCON-EC shall conduct plagiarism check by using appropriate software available in online or offline as per institution policy for authenticity,plagiarize content,originality etc

The following plagiarism detection software is used

- Grammerly (<https://www.grammarly.com/plagiarism-checker>)
- Plagiarism detector (<https://plgiarism-detector.net/>)
- Duplichecker (<https://www.duplichecker.com/>)

- The main work/ research carried out by the author/ investigator's shall be based on original ideas and shall be covered by Zero Tolerance Policy on Plagiarism.
- If plagiarism is detected or found and claimed, then it would be brought under guide and head of institution MKSSS,SNCON-EC, Grievance Redressal Committee and Professional Conduct Disciplinary Committee and The Departmental Academic Integrity Panel of MKSSS,SNCON for necessary and maximum penalty.
- The research work or academic work shall include following content: abstract with keywords, introduction, objective, hypothesis, research methodology, result analysis and interpretation, summary and discussion, conclusions, recommendations and references.
- As per UGC (Promotion of Academic Integrity and Prevention of Plagiarism in Higher Education all Institutions) Regulations, 2017, students, researchers/ investigator and faculty members should not perform any academic misconduct by the theft of intellectual property in any manner.
- The authors/ researcher shall provide proper attribution by citing work of other author work, obtained permission of the other author for using their work wherever necessary and provide acknowledgement of sources.
- In case of found guilty of plagiarizing, they shall be considered under following class of severity as per MUHS and UGC guideline norms. i.e. verification of plagiarism:-
- ✧ On receipt of the draft Thesis / Dissertation from the author, it shall be sent to the Expert, nominated by the head of the institute for verification of plagiarism in the research work in the Thesis/ Dissertation, or which shall be verified through the

software or by any other manner, as per the policy decided by the institute, in that behalf

