Research code ethics

SST'S Ayurved College aims in qualitative research work in field of Ayurveda which should turn out beneficial to Society. Accordingly institute has formulated code of ethics for research following guidelines stated by ICMR. (https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf). Code of ethics has been recently revised twice by IEC dated on 3rd may 2021 3rd September 20212 an.

Salient features of revised code of ethics are as follows.

1. **Prime responsibilities of Researcher:**

- **All clinical trials must obtain approval by institutional ethical committee before their commencement.** Clinical trials must follow guidelines / code of ethics stated by institutional ethical committee.
- All research work must be planned, conducted and reported in a manner that ensures that the dignity, rights, safety and well-being of participants are protected.
- All research works where clinical trial(participation of human subjects) is involved must follow principles-

1. **Principle of essentiality** whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research. This should be duly vetted by an ethics committee (EC) independent of the proposed research.
2. **Principle of voluntariness** whereby respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time,is paramount. The informed consent process ensures that participants' rights are safeguarded.

3. **Principle of non-exploitation** whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured.
4. **Principle of social responsibility** whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.
5. **Principle of ensuring privacy and confidentiality** whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.)privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.
6. **Principle of risk minimization** whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.
7. **Principle of professional competence** whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.
8. **Principle of maximization of benefit** whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society.

9. **Principle of transparency and accountability** whereby the research plan and outcomes emanating from the research are brought into the public domain through registries ,reports and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair,honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/audit.
10. **Principle of totality of responsibility** whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.
11. **Principle of environmental protection** whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

- For research involving human participants, it is the primary responsibility of the researcher to obtain the **written, informed consent** of the prospective participant or legally acceptable/authorized representative (LAR). In case of an individual who is not capable of giving informed consent, the consent of the LAR should be obtained. If a participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process.
- **Adeverse Events if occurs** must be recorded and reported to the EC. The researcher is responsible for reporting all SAEs to the EC within 24 hours of knowledge. All research participants who suffer harm, whether related or

not, will be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc. Medical management will be free if the harm is related to the research. Compensation will be given to any participant when the injury is related to the research, applicable to participants in any of the arms of research, such as intervention, control and standard of care.

- The researcher should safeguard the **confidentiality** of research related data of participants and the community. Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.
- **Conflict of interest (COI)** is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
- Research involved in experimentation on animals must follow all the existing regulations

and guidelines including Guidelines for Care and Use of Animals in Scientific Research (Indian National Science Academy, 1982, amended in 2000), ICMR Guidelines on Humane Care and Use ofLaboratory Animals, 2006, Committee for the Purpose of Control and Supervision of Experiments on Animals (CPSCSEA) Guidelines for Laboratory Animal Facilities, and Guidelines for Rehabilitation of Animals used in Research, 2010.

In order to bring regularity and transparency in research work IEC has set certain rules and regulations for research scholars. (revised on 3rd Sep 2021)

1. It is obligatory for allscholars that their **six months report and log book get checked timely at regular intervals** only. Late submission of six months report will not get considered without any prior informed considerable reason.
2. In context of clinical research, students **must bring their original case papers (OPD/IPD) of registered patients,** get duly signed by respective guide. Then only case proforma will get signed by guide.
3. It is mandatory for students to publish their **dissertation related research work in scientific non predatory journals** only. (**Pubmed indexed/ UGC indexed/Web of science indexed /Scopus indexed)**
4. Before **final submission of dissertation work plagiarism checked certificate** must be attached to it.

2. Ethical Responsibilities of Mentor/Guides:

Mentors, through their experience should guide researchers in ways above and beyond what can be gathered from reading textbooks. The relationship between mentors and trainees should enable trainees to become responsible researchers. Mentors would ensure their trainees conduct research honestly, do not interfere with the work of other researchers and use resources judiciously. A mentor should encourage decision making by the trainees and the trainee should take an active role in communicating her/his needs.

- ✓ Take regular follow up of student's research work.
- ✓ Sign their case proforma only after reviewing original case papers. Then only give sign on log book and six months report.
- ✓ Certify final dissertation only after plagiarism checked certificate and publication in scientific journal only.

3. Guideline for Data collection and publication:

- Research must be conducted following general guidelines and protocols given for clinical evaluation of Ayurvedic interventions (http://www.ccras.nic.in/sites/default/files/viewpdf/Publication/CCRAS_Guideline%20of%20Clinical_Evaluation.pdf.) Implementation of poorly designed research wastes resources and should be avoided. Data protection and storage is important and once collected, data must be properly protected, as it may be needed at a later stage to confirm research findings, establish priority, or be re-analysed by other researchers.
- Research that is completed, irrespective of results, must be published, since it would be unethical to expose another set of participant/patients/volunteers to the same risks to obtain the same results. Registration of research in CTRI ensures that more complete, authenticated, readily available data on research is available publicly. This improves transparency, accountability and accessibility. Hence researchers are encouraged to provide results of study in the public database of the Clinical Trial Registry-India (CTRI). Trial registration involves providing information regarding the study, investigators, sites, sponsor, ethics committees, regulatory clearances, disease/condition, types of study, methodologies, outcomes, etc .
- The researchers must follow the guidance of **International Committee of Medical Journal Editors (ICMJE) on authorship** (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

Authorship must not be gifted and 'ghost' authors are not acceptable.

Research performed as part of a mandatory requirement of a course/fellowship/training programme including student research should have the candidate as the primary author. All efforts must be made to provide the candidate

with an opportunity to fulfil the second, third and fourth criteria of the ICMJE guidelines.

Various ways of Research misconduct Fabrication(intentional act of making-up data or results and recording) **, Falsification(**manipulating research materials, equipment or processes, or changing or omitting/suppressing data or results without scientific or statistical justification), **and plagiarism (**wrongful appropriation" and "stealing and publication" of another

paper or another author's "language,)**are strongly prohibited by institute.**

To keep surveillance on such research misconduct by researchers, IEC has made mandatory to publish their respective research work in non predatory scientific journals only(revised and updated from 3rd May 2021) and for Dissertation must be checked for plagiarism.(revised and updated from 3rd september2021)

4. **Role of Institutional Ethical Committee (IEC)**

- The **IEC is responsible for ensuring that the research is conducted in accordance with the fore-mentioned principles.**
- The IEC should assess the inherent benefits and risks, ensure a favorable balance of benefits and risks, evaluate plans for minimizing the risk and discomfort and decide on the merit of the research before approving it.
- The **informed consent document (ICD), should be reviewed and approved by the EC before enrollment of participants.**
- The EC is responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum and type of assistance to be provided to the participants.
- EC must evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this; and is required that their

members to disclose their own COI and take appropriate measures to rescues themselves from reviewing or decision making on protocols related to their COI; and make appropriate suggestions for management, if COI is detected at the institutional or researchers level.

- While constituting IEC following norms stated in ICMR for composition of ethical committee have been followed.

✓ ECs should be multi-disciplinary and multi-sectoral with adequate representation of age and gender.

✓ 50% of the members should be non-affiliated or from outside the institution.

✓ The number of members in an EC should preferably be between seven and 15 and minimum of five members should be present to meet the quorum requirements.

✓ The EC should have a balance between medical and non-medical members/technical

and non-technical members, depending upon the needs of the institution.

In nutshell code of ethics for research has been designed with utmost care given to breed qualitative research work of optimum standards in field of Ayurveda.