SOP 12: Ethical Guidelines for Application of Artificial Intelligence (AI) in Biomedical Research and Healthcare

Introduction: Incorporation of artificial intelligence (AI) in health care sector has an enormous potential benefit to overcome some major challenges in the complex health care system. Hence the adoption of AI in medical care is growing in India. However AI being data driven technology, has potential ethical issues. Indian Council of Medical Research (ICMR) has developed the frame work to guide the stake holders in ethical conduct of biomedical and health research with application of AI in 2023. Based on it, Shridevi Institute of Medical College Ethics Committee (SMCEC) has incorporated the guidelines for review by ethics committee.

Purpose: The basic four principles of ethics in research - respect for persons (autonomy), do good (beneficence), do no harm (nonmaleficence), and distributive justice, and 12 general principles to ensure the protection of the dignity, rights, safety, and well-being of the community and the participants is applicable to both conventional method and Artificial Intelligence (AI) assisted research. AI is defined as "a system's ability to correctly interpret external data and to use those learning's to achieve specific goal and tasks through flexible adaption". AI for health to a large extent depends on data obtained from human participants and invokes additional concerns related to potential biases, data handling, interpretation, autonomy, risk minimization, professional competence, data sharing, and confidentiality. It is therefore imperative to have an ethical framework that addresses issues specific to AI for biomedical research and healthcare.

Scope: The guidelines apply to AI based tools created for all biomedical and health research and applications involving human participants and/or their biological data.

Responsibility: The guidelines are applicable to health professionals, researchers, hospitals, research institutions, and laypersons who want to utilize health data for biomedical research and healthcare delivery using AI technology and techniques.

Procedure:

12.1: **Responsible AI:-** Inclusiveness, fair, secure, and transparency are core elements of widely asserted responsible AI frameworks.

12.2: Composition of EC:-

12.2.1: SMCEC when frequently deal with AI-technology projects should incorporate legal experts who have experience in IT and medical law, data scientists and computer scientists with expertise in AI technology.

12.2.2: Subject experts may also be invited if AI related proposals are to be reviewed occasionally.

12.3: Members Training:-

12.3.1: Members should be occasionally trained in emerging AI technologies such as big data, deep learning (DL), internet of things (IoT), so that they are informed about these subjects to an appropriate level before they start evaluating proposals for the same.

12.3.2: **Deep Learning (DL):** DL is a subset of machine learning based on artificial neural networks in which multiple processing layers are used to extract higher level features from the data. It can be supervised, semi supervised or unsupervised.

12.4: Roles and responsibilities of the EC:-

12.4.1: SMCEC reviews research proposal, progress and final reports as well as reporting of adverse events and provides suggestions for minimizing the risk to the study.

12.4.2: Recommendations regarding appropriate compensation for research related injury should be made by the SMCEC, wherever it is required.

12.4.3: Monitoring visits at study sites should be carried out by the SMCEC as and when needed.

12.4.4: In case of conflicts during implementation of key ethical requirements, decisions on the trade-off should be evaluated regularly.

12.5: Ethical Principles for AI Technology in Healthcare:- 10 ethical principles for AI in health have been discussed by ICMR – 2023 ethical guidelines on AI. These principles are

patient-centric and are expected to guide all the stakeholders in the development and deployment of responsible and reliable AI for health.

Figure 1: Ethical principles in health

12.6: Ethical review procedures in medical AI:-

12.6.1: Shridevi Medical College Ethics Committee (SMCEC) is responsible for assessing both the scientific rigor and ethical aspects.

12.6.2: It should ensure that the proposal is scientifically sound and weigh all potential risks and benefits for the population where the research is being carried out.

12.6.3: It should check the proposals for data source, quality, safety, anonymity, and/or data piracy, data selection biases, participant protection, payment of compensation, possibility of stigmatization and others.

12.7: Types of review:-The type of review will be based on the type and degree of risk involved and can be exempt, expedited or full committee review as the case may be.

12.8: Ethical issues related to reviewing a protocol: Along with the issues commonly reviewed by SMCEC in conventional research protocol, certain specific additional requirements also to be examined by the committee before taking the decision.

Table 1: Ethical issues related to reviewing a protocol

Sl. No.	Routine issues	Special issues for AI related protocols
1	Essentiality of the study	Essentiality and appropriateness of the system
2	Disclosure or declaration of potential COI	Alternates available and opportunity/cost comparison
3	Scientific design and conduct of study	Qualifications of researchers/ developers
4	Benefit-risk assessment	Training for data collection procedures
5	Recruitment of research participants (Retrospective/ Prospective study)	Selection of training and testing populations
6	Informed consent process	A. Possible technology malfunctions/ glitches/ failures and the redressal mechanisms; B. Stakeholder responsibility and accountability to different aspects of AI technology malfunction / injury
7	Payment for participation (Prospective study)	Adequacy assessment of study sites
8	Protection of privacy and confidentiality including data privacy (both retrospective and prospective)	A. Informed Refusal process B. Data source, participant selection process and quality assessment C. Opportunity to constantly upgrade AI technology with additional data and technology and its influence on participants D. Quality check of the AI technology. E. Participants 'right-to-be forgotten' F. Data storage and sharing policies

12.9: Informed Consent Process:

12.9.1: Informed consent is a process which primarily involves three major components- providing relevant information to prospective participants, ensuring the individual's competence in understanding the given information and voluntariness of participation.

12.9.2: The researcher must obtain written informed consent from the study participant for any health research involving human participants and their data.

12.9.3: The consent should be freely given and not obtained through duress or coercion of any kind, or by offering undue inducements.

12.9.4: In case the participant is not competent (medically or legally) to give consent, the consent must be taken from a legally authorized representative.

12.9.5: At all stages, participants' privacy and confidentiality must be protected.

12.9.6: The potential consequences of breech in privacy should also be mentioned in the informed consent document.

12.10: Responsibilities of researchers:

12.10.1: The Researcher must make sure that the research participants understand the alternatives available (including traditional methods) for the AI technology in question, including doing nothing.

12.10.2: Comparable benefits and risks involved should be discussed.

12.10.3: The Researcher must ensure that the patient/research subject has understood the process and must evaluate the research subject by "teach-back", or "show-me" or any other evaluation technique.

12.10.4: **Teach-back /Show-me Technique:** The teach-back also called the show-me is a communication confirmation technique used by healthcare providers to confirm whether a patient/ care taker understands what is being explained to them. If a patient understands, they are able to "teach back" the information accurately.

12.10.5: The research participant education is a very important step for an on-going process which would be required including if consent obtaining is required multiple times to reduce patient drop-outs. This should also be documented.

12.10.6: The Researcher of the product should be able to distinguish between the role of human caregivers and technology during each part of the procedure. This should be explained clear to the research subject.

12.10.7: The Researcher should clearly explain the possibility of missteps at each level of the procedure and the risk attached to it.

12.10.8: Without prior consent, AI technologies informing significant decisions should not attempt to make value judgments on people's behalf.

12.10.9: When informing an AI subject about important decisions they will make, AI technologies should not unreasonably limit the available options or otherwise attempt to influence their value judgements without the AI subject's consent.

12.10.10: The standard procedure for documentation of informed consent process, electronic consent and specific issues in clinical trials may be followed as per the National Ethical Guidelines for bio-medical and health research, 2017.

12.10.11: IEC approval is required for the use of retrospective data for developing and validating the AI technology.

12.10.12: Waiver of consent - The researcher may apply to the SMCEC for a waiver of consent, if the research involves less than minimal risk to participants and the waiver will not jeopardize the participants' rights and welfare.

12.11: Guidelines for use of AI in writing research:-

12.11.1: AI assisted writing- Content that have been created independently but refined or improved with the help of AI tools. EX- Grammarly, Curie, and LanguageTool.

12.11.12- AI generated writing- AI tool is the primary creator, either text, images or translations, even if the researcher has made significant changes afterwards. EX- ChatGPT, Large language models.

12.11.3- AI generated contents (texts, images, collection, analysis of data and translations) must be disclosed to ensure quality of standard and authenticity in writing.

12.11.4- The author must disclose AI tools used and where the information is located in the research proposal.

12.11.5- AI tools cannot be recognised as co-authors as they cannot take responsibility for the submitted work.

12.11.6- Researchers are accountable for the integrity of the content generated by or with the support of AI tools.

12.11.7- Researchers should maintain a critical approach to using the output produced by generative AI and are aware of the tools' limitations, such as bias, hallucinations and inaccuracies.

12.11.8- Researchers should not use fabricated material created by generative AI in the scientific process, by falsifying , altering or manipulating original research data.

12.11.9: AI generated content in the research proposal should not be more than 25%.

12.11.10: Plagiarism should not be more than 15-20% in any research writing.

Annexure 1: Ethics checklist of AI for biomedical research and healthcare

Sl. No.	Index	Description
1	Objectives	The project's objectives and functioning of the AI tool.
2	Technology	Describe the broad principles of AI technology used and its application (e.g., supervised or unsupervised)
3	Funding & conflict of interest	Notify all sources of funding and who would possibly have an interest or benefit from the AI technology
4	Credentials	Description of Team and individual expertise in AI technology. Describe how these participants will assist in the design, development and validation of AI tool.
5	Type of participants	Describe the participants (Healthy volunteers, Patients, Vulnerable persons/ Special groups)
6	Participant recruitment methods used	The recruiter name (person, organization, etc.) and the recruitment methods considering equity, fairness, representativeness, geographic distribution, and ethnic minorities
7	Risks involved and management strategy	The anticipated physical/social/psychological discomforts/ risk to participants if any may be mentioned and risk management strategy.
8	Treatment of research related injuries	Describe the provision for free treatment/ management for AI technology research related injuries.
9	Potential benefits of AI tool	Describe the potential benefits of AI tool (e.g., for the participants, medical/clinical science, health system, society/community, enhancement of science)
10	Evidence	Provide justification and evidence regarding AI technology in terms of accuracy, validity, efficacy, and performance. Sources of scientific publication, if any, may be added.
11	Validation	Provide details of the validation strategy or methodology run on the AI technology and outcomes of testing under different scenarios/ contexts.
12	Accountability	Describe the complaint redressal procedure and the names of the persons/institutions who will be accountable for the AI tool related actions and associated consequences

13	Monitoring	Process of monitoring unintended consequences and adverse events with the use of AI technology
14	Data collection, storage, sharing and access to data	Describe the source of data, data collection method and storage, data access procedures, and data security
15	Informed consent	1. Describe the type of consent (Signed consent, Verbal/Oral consent, Witnessed consent and Audio-Video (AV) consent). 2. Who will obtain the informed consent (PI/Co-PI, Nurse/Counsellor, Research Staff or Other.)? 3. Mechanism for consent withdrawal.
16	Right to be forgotten	Can a person retrieve and erase all their records or not? And if yes then how? Describe the process.
17	Moderation (human in the loop)*	Does the AI technology require human intervention/ moderation? If yes give proper details for instance, who will control the access to AI technology.

*** Human in the loop (HITL):** It is a branch of artificial intelligence that leverages both human and machine intelligence to create machine learning models. In this people are involved in a virtuous circle where they train, tune, and test a particular algorithm.

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Abbreviations

AI- Artificial Intelligence

DL- Deep Learning

EC-Ethics Committee

HITL- Human In The Loop

ICD- Informed Consent Document

ICF- Informed Consent Form

ICMR- Indian Council of Medical Research

LAR- Legal Authorized Representative

SMCEC- Shridevi Medical College Ethics Committee