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ISSUES AND CHALLENGES FACED BY ETHICS COMMITTEE IN BIOMEDICAL AND HEALTH RESEARCH: INDIAN PERSPECTIVE

Priyanka Dadha — Project Scientist C, ICMR Bioethics Unit, National Centre for Disease Informatics & Research, Bengaluru, India.

P. Uday Kumar — Member Secretary, Ethics Committee and Scientist 'G', Division of Pathology & Microbiology, ICMR-National Institute of Nutrition, Hyderabad, India.

ABSTRACT Ethics Committees (ECs) are interdisciplinary, unbiased classes of entities chosen to evaluate biomedical and health research conventions concerning human lives to make sure the dignity, fundamental rights, safety, and well-being of research participants are appropriately considered and safeguarded. The detailed composition, affiliations, qualifications, member specific roles and responsibilities of an EC is mentioned in ICMR National Ethical Guidelines on Biomedical and Health Research involving Human Participants, 2017. The ICMR-RIPE policy, 2019 is applicable for ICMR and its network of institutes, centres and Divisions mentions that the EC should play a very important role in maintaining the research integrity of a research document in collaboration with RIO, ICMR Bioethics Unit, IPR Unit and other authorities involved. The ECs play vital role in delivering unbiased, honest ethical opinion to management, administration, and the community/society on crucial issues; it is imperative to recognize the challenges confronted by them and the situations and circumstances under which these groups can succeed. The key challenges faced by the ECs of various institutes and those confronted by the authors in the area of bioethics are mostly related to its structure, functioning, training of EC members and investigators, regulatory matters, social apprehensions, conflicts of interest and other relevant associations; decision making capacities, importance to gold standards, lack of facilities and funds, lack of capacity building, non-specific establishment of EC, participant/patient centric approach, influence of investigators/sponsors, review of multi-centric/national research, publication of results, handling research misconduct etc. The ECs ought to have systems and tools for periodic evaluation to measure the quality of their efforts, operation, and performance to find out whether there is a scope for enhancement. Addressing ethical challenges that ECs face needs management at the individual, institutional, community, and global levels and recommends the involvement of governing bodies, and representatives from various cores. The tools and techniques are feedback forms, self-evaluation questionnaire and other structured self-evaluation exercises. The ECs should illustrate the do's (to be done) of the research and explain the don'ts (should not be done) to make it specific and precise to overcome various challenges. It is encouraged that further analysis should be carried out in the form of research to support the development of formal guidance to the identified challenges.

KEYWORDS : Bioethics, fundamental principles, research integrity, ethical challenges, research misconduct.

INTRODUCTION

"The best way to predict the future is to invent it"-Alan Kay

It is a simple assertion that summarizes the sense of importance, demonstrates several prospects of scientific and pioneering sides of biomedical and health research.

The Global Forum for Health Research has indicated that not more than 10% of the world's research reserves are set aside for 90% of the health complications and this is known as "the 10/90 gap"[1]. Health is the foundation stone of growth and development and "good health is a keystone of financial advancement, a multiplier of society's human resources and certainly the principal aim of development"[2]. The essential measures in rectifying this imbalance are to foster equity in health research worldwide and to bolster the capacity to undertake and commence appropriate research[3]. Research grants and funding in emerging nations has also remained the focus of substantial attention[4], thusthe developing and implementation of research must be guided by the underlying fundamental principles of human dignity and ethics. There has been extensive discussion and argument concerning the principled ethical conduct, examine and evaluation of health research and the opinions of public health experts and researchers from evolving countries have been underrepresented[5].

The Biomedical and Health research on human participants stipulates the necessity of regulatory governing authorization for Responsible Conduct of Research. The nations influenced to the British kingdom call these as 'ethics committees', and US-inspired nations have a propensity to call them 'Institutional Review Boards'[6]. In India, the term used for such governing and monitoring body is 'Ethics Committee'(EC); ECs are interdisciplinary, unbiased classes of entities chosen to evaluate biomedical research conventions concerning human lives to make sure the dignity, fundamental rights, safety, and well-being of research participants are appropriately observed and safeguarded. It plays a central part in the research process and can be constituted at community, regional or national level.

The EC members are usually appointed by the head of the institutions and are increasingly provided for by law. There might be certain variations pertaining to the appointment, allocation of duties and functioning of ECs in various parts of the world (USA[7], Europe[8], Australia[9], Newzealand[10], Pakistan[11] etc.) Thus, ECs ought to be established and operate corresponding to established ethical principles and procedural guidelines of the individual territory. In India, the authentic and candid procedures are followed for appointing EC members and make EC self-contained but having comprehensive approach. The detailed composition, affiliations, qualifications, member specific roles and responsibilities of an EC is mentioned in ICMR National Ethical Guidelines on Biomedical and Health Research involving Human Participants, 2017[12]. The quorum requirements for EC meetings can be summed up as: presence of minimum of 5 members (medical/non-medical/technical/non-technical/lay person), one affiliated member should be part of the quorum, CDSCO document to be followed for reviewing clinical trials. They share important characteristics indicating the principles and goals of their duties and responsibilities, possess collective expertise in the fields or disciplines deemed necessary for their work. The member secretary must establish administrative procedures to monitor records at all steps of the evaluation procedure and ensure that all EC members, whether professional members or lay person, have an equivalent importance. This may cause a dispute in associations with a practice of robust regard for power, authority or hierarchy[13,14]. The ECs have their specific role and responsibilities; it plays a progressively valuable role in the conversation with the society regarding ethical aspects of biomedical research. As mentioned in ICMR-RIPE policy, 2019, applicable for ICMR and its network of institutes, centres and Divisions, the EC should play a very important role in maintaining the research integrity of a research document in collaboration with RIO, ICMR Bioethics Unit, IPR Unit and other authorities involved[15]. There is growing nationwide and worldwide attention in confirming that EC review accomplishes the ultimate potential specifications pertaining to the safeguard of research participants and the populations they represent or drawn.

Challenges faced by ECs in India: Bridging the gaps

The establishment of EC is the initial step, and the bigger challenge is to boost their competence to be autonomous, diverse, inquisitive organizations skilled to provide sustainable opinion and guidance related to the research. The term "ethical challenges" primarily implies to ethical predicaments and ethical disagreements along with additional circumstances wherever tough selections need to be done. Ethical predicaments and disagreements are depicted as conditions where judgements are made among two decisions that may be ethically

conceivable but are likewise debatable owing to the circumstances[16]. On the other side of the coin, ethical conflicts begin while one is informed of the obligation of correct actions but may have limitations in exerting these acts as there are other internal or external factors[17]. Taking in account that the most important responsibility the ECs act in giving independent, established ethical guidance on important concerns, it is essential to recognize the challenges confronted by them and the circumstances under which these committees can succeed. The key challenges already faced by the ECs of various institutes and others those confronted by the authors in bioethics are mostly related to its structure, functioning, training of EC members and investigators, regulatory monitoring, social issues and concerns, conflicts of interest and additional related connotations are stated below[18-26]:

Decision making capacities:
- The standard guidelines document that the EC members need to opt for consensus voting and reach to a decision to maintain the dignity of the members. During critical decision-making process it may lead to life threatening consequences.
- The viewpoint of the members of EC may get ignored by decision making authorities; it directs to justify the role played by each member during the meeting, their involvement and display the practicability, publicity, and separation-of-powers.

Importance to gold standards:
- The biomedical and health research involves diagnosis/treatment/ management and other related aspects; mostly the ECs does not get opportunity to review the ethical aspects of clinical practice as the ongoing treatments are gold standard. Hence, this 'grey' region of clinical inspection and its difference from biomedical research is challenging and debatable.
- The ECs are expected to approve the research work in context of achieving the ethical targets rather than utility focused thought.
- There are various validated documents available it sometime leads to confusion as which document to be followed and other/s to be ignored/prioritized.

Lack of facilities and funds:
- Most of the institutions do not provide sufficient time, infrastructure, funds, and resources for smooth and proper functioning of EC.

Lack of capacity building:
- Most of the ECs do not have periodic, authentic training of their all EC members and also do not get their quorum requirements fulfilled.
- The EC member(s) may lack complete understanding of local language and thus cannot give the inputs for the consent form written in the language they do not know.
- Inadequate training of EC members, shortage of standard operating procedures, absence of bioethics in core curriculum, post-trial approach.

Non-specific establishment of EC
- The EC team cumulated to review multiple proposals may not be suitable to review all the proposals in a meeting and leads to partial or insufficient review of the proposal(s).
- The designated quorum of ECs sometimes lacks to review clinical trial due to the lack of appropriate implementation of regulatory documents leads to the inefficient functioning of ECs.

Participant/Patient centric approach
- More importance is given to the parameters related to patients/participants involved not the health care workers/ personnel involved in conducting the study.
- Lack of involvement of the EC in the personnel/staff that will be selected to conduct the study approved by EC. For ex- scientific research ability to cope up during pandemic.

Influence and pressure from investigators/sponsors
- The ECs manage the influence, pressure, and stress from the investigators/sponsors/administration to accept and approve the proposal as the ECs of other collaborative institutes/organizations/ associations have approved it.

Review of multi-centric/national research:
- The objectives or design of the study are very good and are expected to be beneficial for the community, but they do not fit in all the centres, the EC should approve the project till and until it is suitable for all the centres.
- The EC members may not be aware/understanding of the local requirements, cultural and moral values of the population of host or sponsor country to reach to a decision.
- Multicentric studies needs EC approval from multiple sites, some of the sites take approval from the ECs (known as secret societies) that does not meet the criteria of National guidelines and their things cannot even be verified also by other ECs following national guidelines.

Publication of results
- Many times, ethical clearance is taken but it is not renewed again, or it is published after a long gap, it shows that in that period the data has become obsolete, or it needs further renewal.
- The ECs recommend that the outcomes and findings of the research must be published initially only in scientific academic journal. It can be made available to other platforms like media to impart the knowledge and awareness to the society but not for the intention of marketing and promotion but there is no SOP with them to keep a track of the same.

Handling research misconduct
- The EC is expected to provide the administrative arrangements and the solution to address unethical concerns without getting indulged in controversies.

Other challenges
- Performing expedited review and facing legal issues as they get warning letter from higher authorities.
- Some of the reviewers do not review the protocol on time allotted to them, investigators do not report back after expiration of validity of ethical approval / after completion of the study, they do not submit the report/monitoring does not come under EC purview.
- The ECs are the targets to review, approve/reject during uncertain and unplanned (Covid-19 pandemic etc.) and need to manage with available resources.

There are various other critical incidences/challenges where EC members must play a very vital role and seek for the solutions to overcome those issues. To decipher these drawbacks the ECs should keep on organising and undergoing continuous formal trainings and interactive sessions to keep their knowledge updated. For ex- The Helsinki Declaration have declared that there should not be any research usage of placebo in specific conditions, however the Federal Drug Administration have justifiably deemed and judged in 2008 that certain placebo uses in such conditions are ethically acceptable[27,28]. Similarly, ICMR National Ethical Guidelines and handbook published in 1980, 2000, 2006 and 2017 differ significantly in their principles and other content[12, 29-31]. The New Drugs and Clinical Trials Rules, 2019 have come up with updated clauses and laws to be adhered to. Additionally, it imposes that the ICMR guidelines to be implemented, hence implicitly providing these guidelines the importance of a regulation. Even though these regulations and laws were extensively published and disseminated and acknowledged by groups engaged in human research but their execution and application yet continues to be mostly voluntary and deliberate. Besides, independent audit, assessment, or inspection wherever applicable, ECs should have arrangements of mechanism for intermittent evaluation of composition, operation, management and other associated relevant aspects to analyse, interpret and conclude if there is a scope for improvement[32]. The tools and techniques are feedback forms, self-evaluation questionnaire and other structured self-evaluation exercises in western countries as well as in India[18-22].

CONCLUSION:

The ECs have got specialized responsibilities and functions when biomedical research is planned, designed, approved, and conducted, and the research outcomes are assessed and stated, it should certify that the proposed biomedical research must be ethically suitable before being accepted, approved, and published. This will be responsible for community confidence and trust that unfair/unethical research is prevented and fair, ethically perfect research is supported by scientific fraternity.

Addressing ethical challenges that ECs face needs advice and supervision at the local, functional, society, and global levels and urges

the commitment and dedication of regulating groups, and representatives from different cores. The ECs should illustrate the do's (to be done) of the research and explain the don'ts (should not be done) to make it specific and precise to overcome various challenges. Generally, regardless of the citations of issues, challenges and arguments in the published information, guidance on managing some of these ethics disputes is scant. It is encouraged that further analysis should be carried out in the form of research to sustain the advancement of official support to the associated recognized tasks and challenges. Various international and national policies and guidelines can be used a reference and may prove to be beneficial and depict that ECs play a key role in conduct of research.

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