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Characteristics of Institutional Ethics Committees and the Implementation of SOP (Standard Operating Procedure) Frameworks across Institutions in Northeast India

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Abstract

Research institutions in North East (NE) India provide very little publicly available information about their institutional ethics committees (IECs) or the standard operating procedures (SOPs) that guide them. To address this gap, a review was carried out across fourteen biomedical and health research institutes in the region. Only twelve of these had formally created IECs. These committees drew members from varied professional backgrounds and sectors, yet only eight institutions demonstrated age diversity and only seven showed balanced gender representation. In nearly all committees (11 of 12), the chairperson came from outside the host institution, and in ten cases their qualifications aligned with the requirements outlined in the Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. Half of the IECs lacked a lay person altogether. SOPs existed in nine of the institutions; however, only three of these covered the full spectrum of protocol review categories—exemption, expedited review, and review by the full committee. Six SOPs called for quarterly meetings, and seven explicitly mentioned declaration of conflict of interest (CoI). Five specified that members with a CoI could not vote, while seven described logistical provisions such as office space, staffing, and budgeting. Notably, just two of the twelve IECs had completed the registration process. Overall, the assessment shows that IEC structures and their governing SOPs in NE India remain far below recommended standards, with most committees not adhering to provisions laid out in the ICMR 2017 guidelines and many still unregistered.

Keywords: Standard operating procedure, Institutional ethics committee, North east India

Introduction

The expanding landscape of biomedical and health research has placed intensified ethical responsibilities on investigators, institutions, and ethics oversight bodies. Within this environment, the institutional ethics committee (IEC) becomes a central mechanism for safeguarding the dignity, rights, and welfare of individuals participating in research. Any biomedical and health research Institute (BHRI) that undertakes work involving human participants is obligated to establish an independent IEC and to operate it according to a written standard operating procedure (SOP) [1]. When creating IECs and formulating SOPs, BHRIs are instructed to follow the Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, and the Drugs and Cosmetics Rules, 1945 (GOI, DC rules 1945) in the case of studies involving drugs or devices [1, 2].

Episodes of unethical conduct toward vulnerable groups have contributed to public dissatisfaction and a decline in trust in research practices [1]. India has recorded several cases where marginalised communities were exposed to exploitative or poorly governed research activities—often described as ethics dumping [3]. Regulatory approval is not required for non-drug investigations [2], and institutions such as the Medical Council of India (MCI) and the Central Drugs Standard Control

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Organisation (CDSCO) exercise limited oversight of IECs in non-regulatory academic research. Following a ruling by the Supreme Court of India, however, the Ministry of Health and Family Welfare (MoHFW, GOI) instructed all IECs conducting regulatory research to register with the CDSCO [2].

Although the MCI now includes peer-reviewed publications as a criterion for academic advancement [4], there is no parallel requirement ensuring the quality of ethical review systems. This omission, combined with longstanding issues in institutional governance, has weakened core values essential to responsible research [5]. Protection of human participants relies heavily on IECs that are well-constituted, properly trained, and able to review proposals independently [1]. Yet IEC-related infrastructure in India remains weak: more than half of the research institutions reportedly lack formal committees and continue to struggle with shortages of trained personnel, inadequate workspace, insufficient administrative support, large review burdens, poorly articulated or absent SOPs, and non-compliance with Schedule Y directives governing trials under the Drugs and Cosmetics Act [6-9].

According to Kumar NK in an ICMR report, the North Eastern region has historically experienced limited biomedical and health research activity due to sociopolitical instability and inadequate exposure to bioethics training [7]. Strengthening ethical capacity among IEC members and emerging researchers in NE India is essential for improving both research quality and oversight. Therefore, this study was undertaken to document the current condition of IECs and the SOPs guiding biomedical and health research institutes in the region.

Objective

The study sought to map how IECs in biomedical and health research institutes of NE India were organised and to examine the status of the SOPs guiding their operations.

Materials and Methods

Study design

During a six-month window in 2018, a cross-sectional assessment was carried out across institutions in NE India involved in research with human participants. All medical colleges that were recognised by the MCI at that time, along with public biomedical research centres and referral facilities in Assam, formed the universe of interest. Only twelve medical colleges in this region had MCI recognition during the study period.

From this wider frame, fourteen biomedical and health research institutes agreed to participate and supplied either their most recent IEC notifications, their SOPs, or both. The group consisted of twelve MCI-recognised colleges from Assam, Manipur, Meghalaya, Tripura, and Sikkim, in addition to two institutions based in Assam—an ICMR research centre under MoHFW, GoI, and an Air Force Hospital under the Aviation Ministry, GoI. Because Nagaland and Mizoram had no MCI-recognised colleges at the time, they did not contribute any IECs to the study.

Data collection procedure

Institutional permission was requested from administrative heads before collecting documents relevant to their IECs. IEC notifications and SOPs were gathered through repeated contact with Member Secretaries, senior faculty, or institutional leaders. When accessible, documents were also downloaded directly from official websites.

A structured questionnaire, pre-tested and aligned with ICMR 2017 guidelines [1], was used to extract details from each document set. Materials reviewed included the most current IEC notifications for research involving human participants and the prevailing SOPs used within medical colleges, research institutes, and referral hospitals. The questionnaire captured information relating to committee structure, member background and affiliation, procedures for reviewing protocols, record-keeping practices, and administrative and financial arrangements. Inclusion was limited to Institutional Ethics Committees Human (H) that were willing to share their most recent documents or permitted retrieval from their public portals. IECs operating in colleges without MCI recognition or still waiting for their letter of permission were removed from the sample.

Data analysis

The collected IEC documents were analysed through desk review. Each set of observations was then aligned with expectations drawn from the ICMR 2017 guidelines, which functioned as the comparative standard [1]. Institutional anonymity was preserved by stripping identifying information from the dataset. All data processing was completed using Statistical Software and

MS Excel 2010, and results were compiled using MS Word 2010.

Ethics clearance

Approval for this work was granted by the IEC (H), Jorhat Medical College and Hospital, Jorhat, Assam.

Results and Discussion

State-wise status of IECs and SOPs

Across the fourteen participating biomedical and health research institutes, twelve had formally announced the formation of their IECs. All institutes from states other than Assam had active committees in place; in Assam, six of eight institutes had established theirs.

Only nine of the twelve IECs had produced SOPs. A state-level view showed SOP preparation in four of the eight institutes in Assam and one of the two in Tripura, while both institutes in Manipur and one each in Meghalaya and Sikkim had developed SOPs for all of their committees.

A review of institutional websites revealed that six of eight institutes had made their SOPs publicly accessible. However, two of the four in Assam and one of the two in Manipur had posted incomplete versions.

Characteristics and composition of IECs and IEC members

All twelve IECs consisted of members drawn from multiple disciplines and sectors. Eight IECs included a spread of age groups, while seven reflected balanced gender representation. Membership numbers varied between seven and fifteen. Only six committees demonstrated proportional representation between medical and non-medical or technical and non-technical members.

Table 1. Profile and membership structure of IECs in relation to ICMR 2017 requirements (n = 12*)

Characteristics	Count	Percentage
IECs drawing members from multiple academic disciplines	12	100
Committees incorporating representation from diverse professional sectors	12	100
Committees exhibiting a broad distribution across age groups	8	66.7
Committees showing sufficient representation of different genders	7	58.3
Extent of non-affiliated membership within IECs		
Committees where at least half of the members were external to the institution	4	33.3
Committees where fewer than half of the members were non-affiliated	8	66.7
IECs composed of 7–15 members, as recommended	12	100
Committees maintaining proportional inclusion of medical vs. non-medical / technical vs. non-technical members	6	50
Chairperson affiliation status		
Chairpersons not connected to the host institution	11	91.7
Chairpersons drawn from within the institution	1	8.3
Institutions without a functional IEC	2	—

An analysis of IEC composition revealed that 11 out of 12 committees appointed chairpersons who were external to the host institute, with 10 of these 12 chairpersons meeting the qualification criteria outlined in the ICMR 2017 guidelines. Less than half of the members were non-affiliated in eight of the IECs. All member secretaries were affiliated with their respective institutions, and their qualifications complied with ICMR standards. Similarly, basic medical scientists and clinicians in 11 IECs were institution-affiliated, fulfilling the professional requirements of the ICMR 2017 guidelines.

Regarding legal experts, eleven committees included individuals from outside the host institute, all of whom held qualifications consistent with ICMR specifications. Social scientists, philosophers, ethicists, and theologians were represented in 10 IECs, and nine of them were non-affiliated; however, no documentation of their qualifications was available in the IEC notifications or SOPs. Only six IECs included lay members, all external, with the qualifications of three of these members not recorded.

Assessment of the SOPs showed that seven of nine specifically mentioned quorum requirements as per ICMR 2017 guidelines. In terms of appointments, 11 IECs had members selected by the head of the host institution, while in one instance, appointments were made by the Under Secretary to the Government.

Among the nine SOPs reviewed, five indicated a committee term of 2–3 years, whereas one SOP did not specify any tenure. Provisions for honorarium were included in five SOPs, while two SOPs did not mention it. Training of IEC members was addressed in five SOPs, with four offering no reference to training. Finally, eight out of twelve SOPs defined the roles and responsibilities of committee members **(Table 2).**

Table 2. Affiliation, qualification of IEC members (n=12)

S. No	Members of IEC/ Characteristics	Yes (%)	No (%)
1	**Chairperson**		
	· Non-affiliated Chairperson	11(91.7)	1(8.3)
	· Qualifications of Chairperson as per ICMR Guideline 2017	10(83.3%)	2(16.7)
2	**Member Secretary**		
	· Affiliated	12(100)	0
	· Qualifications as per ICMR Guideline 2017	12(100)	0
3	**Basic Medical Scientist**		
	· Affiliated	11(91.7)	1(8.3)
	· Qualifications as per ICMR Guideline	12(100)	0
4	**Clinician**		
	· Affiliated	11(91.7)	1(8.3)
	· Qualifications as per ICMR 2017 guidelines	12(100)	0
5	**Legal Expert/s**		
	· Affiliated	1(8.3)	11(91.7)
	· Qualifications as per ICMR 2017guidelines	12(100)	0
6	**Social Scientist/Philosopher/Ethicist/Theologan**		
	· Affiliated	1(10)	9(90)
	· Not present	2(16.6)	
	· Qualifications as per ICMR 2017 guidelines stated	0	12(100)
7	**Lay person(s)**		
	Status	Numbers	Percentage
	· Non-affiliated	6	50
	· No Layperson	6	50
	Qualifications as per ICMR 2017 guidelines	3	50
8	**Quorum requirements specified in SOPs as per ICMR 2017 guidelines (n=9*)**		
	· Yes	7	77.8
9	**Terms of references for IEC members**		
	Selection/appointment process to committees (n=12)		
	· Appointed by Head of the institute	11	91.7
	· Others	1	8.3
	Term of IEC membership (n=9*)		
	Tenure of IEC membership · < 2 years	1	11.1
	· 2-3 years	5	55.6
	· >3 years	2	22.2
	· Not mentioned in SOP	1	11.1
10	**Honorarium (n=9*)**		
	Provision of Honorarium to IEC members for attending meeting	Numbers	Percentage

	· Yes	5	55.6
	· No provision of honorarium	2	22.2
	· Not mentioned in SOP	2	22.2
11	**Training (n=9*)**		
	Provision for Training of IEC members specified in SOP		
	· Yes	5	55.6
	· Not mentioned in SOP	4	44.4
12	**Roles and responsibilities (n=9*)**		
	Roles and responsibilities of IEC members defined in SOP		
	· Yes	8	88.9
	· No	1	11.1

*Excluded those who did not constitute IECs and had no SOPs

Submission and review procedure

Analysis revealed that among the nine SOPs reviewed, just five provided details on the documents and checklist that investigators are expected to submit along with their research proposals **(Table 3)**.

Table 3. Submission and review procedures for research proposals (n = 9) *

S. No	Characteristics as per ICMR 2017 Guidelines	Percentage (%)	Frequency
1	**Checklist of documents required for IEC submission**		
	Checklist available	55.6	5
	Checklist not available	44.4	4
2	**Details of documents to be included in the protocol**		
	Specified in SOP	77.8	7
	Not specified	22.2	2
3	**Type of IEC review mentioned**	Percentage	Yes
	All three review types indicated	33.3	3
	Only two review types indicated	55.6	5
	No review type mentioned	11.1	1
	Total instances recorded	100	14

*Excludes SOPs from institutes that did not constitute IECs

Among the nine SOPs analyzed, only three committees outlined that they would use all three review formats—full review, expedited review, and exemption from review. Interestingly, one SOP did not specify any review type at all, and five SOPs limited their description to just two formats: full and expedited review.

Meeting frequency

Examination of the SOPs revealed that six IECs planned to meet four times annually to evaluate research proposals, while three SOPs did not indicate how often meetings would be held.

Conflict of interest, voting, and decision processes

In terms of conflict of interest (COI), seven SOPs required members to declare any potential COI in writing to the IEC chairperson. Only five SOPs explicitly stated that members who had declared a COI would refrain from voting. Regarding decision-making, seven IECs relied on consensus among board members, whereas one SOP indicated that decisions would follow a majority vote system.

Records and archiving

It was noted that eight SOPs included instructions for maintaining and archiving records, but there was no standardized approach: retention periods ranged from 5 to 15 years.

Administrative support and budget

Regarding infrastructure and resources, seven SOPs confirmed that IECs had access to dedicated office space,

supporting staff, and a budget to facilitate their operations.

Registration and accreditation

Only two out of the 12 IECs in the NE region were officially registered and accredited, with just one IEC having completed the renewal of registration.

State-wise status of IECs and SOPs

The study assessed the composition of IECs and the availability of SOPs in NE Indian health research institutions. Most institutes had set up IECs to oversee biomedical research involving human participants, with proper notification issued. Assam reported the lowest coverage, with only 75% of its institutes having constituted IECs. Previous studies [6, 10, 11] have similarly observed that, despite the existence of guidelines, several institutes either lacked an IEC entirely or relied on affiliation with a nearby committee. Factors contributing to the absence of IECs in Assam included insufficient trained personnel, lack of awareness, limited administrative attention, and the absence of a legal framework.

Regarding SOPs, only three-quarters of IECs in the NE region had documented procedures. By contrast, a survey in Egypt [12] found that 83.3% of ethics committees had SOPs in place. In Assam and Tripura, half of the IECs had not developed formal SOPs, echoing findings from sub-Saharan Africa [13]. The lack of written SOPs can result in inconsistent processes for submission, approval, and monitoring, potentially weakening ethical oversight and compromising participant rights, safety, and well-being [5].

Furthermore, publication of IEC notifications and SOPs on institutional websites was irregular and generally low in the NE region, particularly in Assam and Tripura. As these documents are non-confidential, they are expected to be publicly accessible [14], but this practice remains largely unimplemented in many institutions.

Characteristics and composition of IECs and their members

An evaluation of the 12 available IECs revealed that all were multidisciplinary and multisectoral, in line with the ICMR 2017 guidelines [1]. However, many committees fell short in terms of age and gender diversity. A study from South Africa reported that in 83 percent of health research ethics committees, women made up less than half of the members [15]. In the current study, IEC sizes ranged from 7 to 15 members, and in half of the committees, there was an imbalance between medical and non-medical, technical and non-technical members. Similar trends have been observed internationally: in Thailand, IECs averaged 14 members, mostly scientific [16], and Saito T [17] reported that many Japanese medical school committees were inappropriately constituted, recommending more external, younger, and female members.

These findings suggest that NE Indian health research institutes may either be unaware of the ICMR 2017 composition requirements [1] or insufficiently motivated to comply. Additionally, most Indian medical schools lack formal bioethics training at graduate and postgraduate levels, and training external members in bioethics remains challenging. Consequently, there is a growing demand for bioethics-trained professionals in India [5, 18].

In most IECs, Chairpersons were appointed externally, and their qualifications complied with ICMR 2017 standards [1]. By contrast, a 2009 study in Delhi public sector teaching hospitals found that only 71.4 percent of IEC Chairpersons were affiliated with their institutions [10]. According to ICMR guidelines, ≥50% of IEC members should be non-affiliated, but in this study, 8 of the 12 IECs had fewer than 50 percent non-affiliated members. All member secretaries, and most basic medical scientists and clinicians, were affiliated with their institutes, while legal experts were generally external. The qualifications of member secretaries, medical scientists, clinicians, and legal experts met the required standards.

The inclusion of social scientists, philosophers, and theologians was noted in 10 of the 12 IECs, with most being non-affiliated. Their qualifications, however, were not reported in notifications or SOPs. Previous studies have similarly emphasized the importance of appropriately constituted committees [19], though a 2000 ICMR study noted frequent absence of legal experts and questionable appointment procedures [7].

Lay person representation was limited, with half of the IECs lacking such members. Earlier literature indicates that lay members may feel intimidated by more powerful scientific members [5], and their absence remains a significant limitation [19]. This may be partly due to low perceived importance or the interpretation of Schedule Y [8] as not requiring laypersons as essential members.

Quorum formation is another critical aspect of IEC functioning. Two SOPs did not specify quorum

requirements, highlighting inadequate attention to this issue. As per ICMR 2017, a minimum of five members should be present, including medical, non-medical/technical, and non-technical members, with at least one non-affiliated member, preferably a layperson [1, 7, 18]. Meetings conducted without a quorum may lack validity.

Most IEC members were appointed by the head of the institute, except in one instance where the undersecretary to the state government acted as the appointing authority. The head of the institute serves as an appellate authority in disputes or appointments [1].

The tenure of IEC membership varied from ≤2 years to ≥3 years, with the standard term generally being 2–3 years. SOPs allow for extensions, and it is considered good practice to rotate a defined percentage of members regularly, promoting broader participation and experience sharing [1, 8, 19].

More than half of the ethics committees provided financial honoraria to members for attending meetings, reflecting trends reported in earlier studies [9, 10, 12]. The ICMR 2017 guidelines recommend that members receive a reasonable honorarium to encourage consistent participation and accountability [1].

Training opportunities, however, were limited, with only five out of nine SOPs including provisions for member education. Previous studies have similarly highlighted inadequate training in IECs [9, 10, 14, 18, 19]. Comprehensive training should encompass participant protection, committee functions, SOP compliance, ethical principles, Good Clinical Practice guidelines where applicable, and national regulatory requirements, [1, 7, 9, 18]. Our findings suggest an urgent need to enhance training programs for IEC members in the NE region.

Roles and responsibilities

The majority of SOPs included clear definitions of IEC member duties. According to ICMR 2017, these responsibilities should be clearly documented in the SOPs and communicated at the time of member appointment [1].

Submission and review procedures

Many IECs lacked a standardized checklist for documents that researchers must submit alongside proposals. Where checklists were available, they adhered to ICMR 2017 guidance [1].

Review types

The SOPs varied in the types of ethical review specified. Only three committees indicated adoption of all three review categories—full, expedited, and exemption from review. None of the SOPs explained who decides the type of review or the criteria used for classification. As per ICMR guidelines, the Member Secretary or Secretariat is responsible for screening proposals and assigning the appropriate review type based on associated risks [1]. Strengthening these procedures is critical for maintaining robust ethical oversight [19].

Meeting frequency

Six SOPs stated that IECs would meet quarterly, while three did not specify meeting schedules. Earlier studies have reported 2–6 meetings per year, sometimes held as needed [10], with infrequent meetings noted as a significant ethical concern [18]. Delays in proposal review may lead to funding withdrawal, decreased chances of future grants, and higher research costs [11]. Optimal practice requires regular meetings, efficient procedures, and minimized turnaround times to avoid delays in research approval [1].

Conflict of interest (COI) and decision-making

Disclosure of COI is mandatory for both IEC members and researchers. Declared COIs should be submitted in writing to the chairperson before the meeting and recorded in the minutes. Members with COI should abstain from decision-making and ideally leave the meeting room during discussions of the affected proposal [1]. Presence of conflicted members may compromise impartial review [10, 19].

Most SOPs explicitly required COI disclosure to the IEC chairperson, but only five SOPs mentioned that conflicted members cannot vote. Previous reports [16] reveal inconsistencies: in some IECs, conflicted members were asked to leave, while in others they remained but could not vote. These discrepancies indicate that SOP drafters may have lacked adequate training or motivation, failing to fully adhere to standard guidelines.

In terms of decision-making, most IECs relied on consensus, with one using a majority vote, in line with ICMR 2017 recommendations [1].

Record keeping and archiving

Most SOPs in our study included provisions for document retention and archiving of IEC-related

materials. However, the specified duration varied considerably, ranging from 5 to 15 years. Inadequate record maintenance remains a notable concern affecting IEC operations [18]. The ICMR 2017 guidelines emphasize that all IEC communications and documents should be dated, properly filed, and preserved according to formal procedures. Specifically, records should be archived for three years after study completion, while documents related to regulatory clinical trials must be retained for at least five years or as stipulated by applicable regulations [1].

Administration and budget

Seven of the nine IEC SOPs provided for dedicated office space, staff support, and budget allocation. A 2009 survey of public sector teaching hospitals in Delhi by Singh S found that 71% of IECs had adequate administrative support, whereas 43% faced insufficient or absent financial backing [10]. Previous studies have highlighted that resource limitations can significantly restrict the effectiveness of research ethics committees globally [20]. According to ICMR 2017 guidelines, all IECs should have independent office infrastructure, dedicated personnel, and a budget [1]. Thus, there remains considerable scope to enhance administrative capacity of IECs in the NE region by providing adequate infrastructure, ensuring members' time is allocated appropriately, and maintaining a clear budgetary provision.

Registration and accreditation

Alarmingly, most IECs in the NE region were neither registered with CDSCO nor accredited, making them ineligible to oversee regulatory clinical trials. The Drugs and Cosmetics Rules, 1945 mandate that no IEC may approve a clinical trial protocol without prior registration with the licensing authority (clause b, rule 21) and require registration renewal every three years to maintain eligibility (2). Our findings indicate that few IECs had renewed registration, reflecting a suboptimal state of IEC readiness in the NE region, and regulatory trials are seldom conducted.

Study limitations

This research was limited to MCI-recognized medical colleges in the NE region and two Government of India health research institutes in Assam. IECs from private institutions were not included, and Nagaland and Mizoram lacked MCI-recognized medical colleges at the time of the study. Additionally, two institutes had not constituted IECs and three IECs had not prepared SOPs, limiting our ability to fully assess their composition or SOP status. Therefore, the results cannot be generalized to all IECs in the NE region.

Conclusion

The study reveals that the composition and operational characteristics of many IECs in NE India are below recommended standards and that a majority are unregistered and not fully aligned with ICMR 2017 guidelines. Consequently, the ethical review mechanisms for research involving human participants in these institutions are weak, representing a significant ethical concern.

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