**Abstract**

**Profile of Institutional Ethics Committees and Status of Standard Operating Procedures in North East India**

Limited data are available regarding Institutional Ethics Committees (IECs) and their Standard Operating Procedure (SOP) in North East (NE) India. Attempt made to know the profile of IECs and Status of SOPs in health research institutes of NE India. Fourteen biomedical and health research institutes of NE India were reviewed.Only 85.7% institutes had constituted their IEC. The IECs were multi-disciplinary and multi-sectorial in nature with adequate representations of age in 66.7% and gender in 58.3%. In 91.7% IECs Chairpersons were non-affiliated and Chairpersons qualifications in 83.3% were found at par with the ICMR guide line 2017. 2/3rd (64.3%) institutes had framed their SOPs. 33.3% IECs adopted all three types of reviews. 66.7% SOPs kept the provision of quarterly review meetings. Declarations of Conflict of Interest (COI) were specified in 77.7% SOPs. 55.6% SOPs mentioned about no voting power of members who declared COI. 77.8% SOPs stated about the designated office space, staff and budget. Only 14.3% IECs were registered. Our findings concluded that the characteristics and composition of IECs of heath research institutes in NE India is suboptimal. Most of the SOPs were not framed as per recommendations of National Ethical Guideline for Biomedical Health Research, ICMR 2017 and unregistered.

Key words: Institutional Ethics Committee, Standard Operating Procedure, North East India

**Title**

**Profile of Institutional Ethics Committees and Status of Standard Operating Procedures in North East India**

1. **Dr Bishnu Ram Das ,**

Professor and Head

Department of Community Medicine

Jorhat Medical College

Jorhat-785001, Assam, India

Phone no +919435020324

Email: [drbishnu07@yahoo.co.in](mailto:drbishnu07@yahoo.co.in)

1. **Dr Gitali Kakoti**

Women Scientist, DHR

Department of Community Medicine

Jorhat Medical College, Jorhat-785001

Assam, India

Phone No +919435580593

Email: [kgitali@yahoo.in](mailto:kgitali@yahoo.in)

**Introduction:**

Rapid growth of Biomedical and Health Research in the current globalised era have added newer responsibilities to researchers, research conducting institutes and ethics committees. In this context appropriately constituted a functional Institutional Ethics Committee (IEC) has significant role to protect the dignity, rights, safety and well-being of research participants. Each Biomedical and Health Research Institute (BHRI) where researches are being conducted involving human participants is accountable for constituting an independent IEC and should have a written Standard Operating Procedure (SOP) according to which the committee should function (1). All BHRIs are required to refer the recently published ICMR guidelines in constituting their IECs and framing the SOPs to review all research protocol involving human participants and the Center for Drugs Standard Control Organization (CDSCO) guidelines for drug and device trials in India (1, 2).

In recent years there have been resentments among the public for compromising the Responsible Conduct of Research by exploiting the potentially vulnerable research participants. The unethical behavior of research conducting agencies can cause damage to public’s trust in research and on the researcher (1). Indian continent has been documenting several incidents of ethics dumping by social exploitation of the marginalized weaker and vulnerable research participants (3).

The licensing authorities have not made it mandatory to take regulatory permission in case of non drug trials (2). Even the regulatory bodies like Medical Council of India (MCI)/CDSCO have little or no control over IECs in academic medical institutes for non regulatory research. Lately following verdict of Supreme Court of India the Ministry of Health and Family Welfare, Government of India (MH&FW, GOI) has directed all the IECs to register with the CDSCO who involve in regulatory research (2).

In recent times, MCI have made it compulsory to include peer reviewed research publications as one of the criteria for career advancement in medical colleges of India (4). However, no criteria have specified to see the standard of ethical review and monitoring. All these have compromised the fundamental values of research (5).

The researchers and ethics committee members ought to be aware of and comply with the scientific, medical, ethical, legal and social requirements of the research proposal (1). The success of the protection of research participants mostly depends on the existence of appropriately constituted functional IECs and their independence to deal with ethics applications (3).

Institutional mechanisms for ethical review of research involving human participants in India are weak and vulnerable (5). In spite of having National Ethical Guidelines more than 50% research institutes in India reportedly lack official IECs and are still struggling with basic issues like, lack of trained manpower, lack of space, poor administrative support, heavy work load unsatisfactory or no SOPs and nonconformity with the schedule Y recommendations (6,7,8,9).

In an ICMR study Kumar NK stated that limited researches have been conducted in past in the field of biomedical and health sciences in NE India because of the law and order issues. Similarly there were fewer awareness/training progarmmes on bioethics (7).

To bring up research standard and its review by IECs it is utmost necessary to build capacity in bio-ethics and ethics committee administration among the IEC members and young researchers of Medical Colleges/biomedical and Health research institutes of NE India. Thus it was contemplated to conduct a study to understand the current status of IECs and their SOPs of biomedical and health research institutes located in this region.

**Objectives:**

To assess the composition of IECs and status of Standard Operating Procedure of IECs in biomedical and health research institutes of NE India

**Methods:**

**Study Design**

A cross-sectional institutional based observational study was conducted over a period of 6 months in 2018. In this study we enlisted all the MCI recognised Medical Colleges, in NE Region of India and Bio-medical research organizations/referral hospitals in public sector in Assam where biomedical research are being conducted. There were only twelve MCI recognised Medical Colleges in NE region at the time of our study.

We enrolled 14 biomedical and health research institutes who have given consent to participate in this study and from whom we could obtain the latest IEC notification and or SOPs. Among them twelve were MCI recognised medical colleges in NE states namely Assam, Manipur, Meghalaya, Tripura and Sikkim and conveniently incorporated one Health Research Institute of ICMR under MH&FW, GOI and one Air Force Hospital under Aviation Ministry of GOI located in Assam. There were none MCI recognised Medical College in Nagaland and in Mizoram at the time of our study.

**Data collection procedure**

We approached administrative head of all these institutes for obtaining administrative clearance to incorporate their IECs and SOPs in the present study. All possible efforts were made to collect the notification of IECs and SOPs through email from the Institutional Head or Member Secretary or through the faculty members working in respective institute. An effort was also made to download the notification of IECs and SOPs from the respective institute’s web site if the same have been made available in public domain.

A pre designed and pretested questionnaire was used to collect data in the line of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants of ICMR, 2017 (1). Study materials used were latest notification of IECs for human participants and up to date version of SOPs of IECs of respective Medical College/Research Institute/Referral hospital. The information collected were composition of IECs, affiliation and qualification of IEC members, review procedures and records keeping, financial and material status. In order to simplify the study and to minimise error, we have specified the inclusion criteria that the IECs (H) willing to provide latest IEC notification and or SOP of IEC (H) or giving permission to download if the said materials are available in their institute website for public use. We excluded those IECs of Medical colleges which were not recognized by MCI or under process of obtaining letter of permission at the time of our study.

**Data analysis**

Desk evaluation of the collected IEC notifications and SOPs were done. Tabulated results were compared during discussion with the the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants of ICMR, 2017 which was taken as gold standard (1). Strict confidentiality was maintained while handling the dataset and Institute names were delinked. Data were processed and analyzed using Statistical Software, MS Excel 2010 and documented using MS Word 2010.

**Ethical Clearance**

Due permission was obtained from the IEC (H), Jorhat Medical College & Hospital, Jorhat, Assam

**Results:**

**State wise Status of IECs and SOPs**

It has been revealed that of the 14(Fourteen) biomedical and health research institutes only 12 (85.7%) had constituted their IEC (H) and it was officially notified. Among them except Assam the entire health research institutes (100%) had their own ECs in place. In Assam only 75% (6/8) health research institutes have constituted their IECs.

As far as SOP is concerned it was found that only 64.3% IECs in research institutes in NE region had framed their SOPs. State wise availability of SOPs confirmed that in Assam and Tripura 50% institutes had structured their own SOPs. While in Manipur, Meghalaya and Sikkim had 100% SOPs in all their IECs.

In this study, we also looked for displaying of SOPs in their respective institutional web sites. It was found that overall 66.6% institutions have displayed their SOPs in their institute website in public domain. Among these Assam was in the lowest level 25%, Manipur and Tripura at middle level 50% each, Meghalaya and Sikkim at highest level 100% each have been displaying their SOPs in their institute web site.

**Characteristics and Compositions of IECs and IEC members**

A majority (85.7%) of health research institutions constituted their IECs by their administrative head and they were notified officially. All the IECs 12(100%) were multi-disciplinary and multi-sectorial in nature. Adequate age representations were seen in 8(66.7%) while adequate gender representations were seen only in 7(58.3%) of the IECs (Table-1). In all (100%) IECs numbers of IEC members were ranges in between 7 to 15. The balance between medical and non-medical/technical and non-technical members were seen in 50% of the IECs.

In regard to non affiliation of Chairpersons it was found that majority 91.7% IECs had non-affiliated Chairpersons and 83.3% Chairpersons qualifications were found at par with the ICMR guide line 2017. Nearly 67% IECs had less than 50% non-affiliated members. All the member secretaries were found to be affiliated to host institutes and their qualifications were according to ICMR standard. Basic Medical Scientist (91.7%) and Clinicians (91.7%) of IECs were affiliated to the host institute and their qualifications were according to ICMR guidiline2017.

In regard to affiliation of the legal experts it was found that 91.7% legal experts were non-affiliated (outside the host institute). The qualifications of all the legal experts (100%) were as mentioned in ICMR guideline.

Social Scientist/Philosopher/Ethicist/Theologians were found only 83.3% IECs. Among these 90% were non-affiliated. The qualifications of these members were mentioned neither in the IEC notification nor in SOPs of ethics committees.

Lay persons were found only in 50% of the available ethics committees and they were non affiliated members. Of these qualifications of 75% lay members were not known. On the other hand in 50% of the available IECs without having any lay persons.

We enquired to find out whether there was any written statement in SOPs about the Quorum requirements during IEC meetings as specified in ICMR guideline 2017 and found that 77.7% had specifically mentioned the requirement of quorum in the respective SOPs. Contrary to this, 22.2% did not mention the requirement of quorum.

It has been observed that in 91.7% IECs the members were appointed by head of the host institute. While in one the appointment (8.3%) was issued by Under Secretary to the Govt.

In 55.6% IECs the term of the committee was 2-3 years. The term was less than 2 years in 11.1% and more than 3 years in 22.2% IECs. The tenure of IECs was not mentioned in 11.1% SOPs.

Provisions of honorarium to IEC members for attending meeting were evaluated and it was found that provisions for honorarium were kept only in 55.6% IECs. There was no mention about honorarium provisions in 22.2% SOPs and similarly provisions not kept in another 22.2% IECs.

Provision of training of IEC members specified in 55.6% SOPs. Conversely, 44.4% SOPs did not mention about the training provisions for IEC members. Roles and responsibilities of IEC members defined in 88.9% SOPs. While no mentioned were seen in 11.1% SOPs (Table-2).

**Submission procedure**

Mention about details of documents to be submitted for IEC review were explored. It was observed that only 55.6% ethics committees had their own check list with their content to be used by the researcher while submitting research proposal to IECs and the contents of the check lists were seen as per ICMR guide line 2017. It was further revealed that the details of the documents to be included in the protocol were spell out only in 77.8% SOPs (Table-3).

**Review procedure adopted**

In regard to type of review procedure of the IECs it was found that 33.3% IECs adopted all the three types of review namely full review, expedited review and exemption from review. On the other hand 55.6% SOPs mentioned that only two type of review will be adopted (Full review and Expedited review). To our surprise 11.1% SOPs of IECs did not mention the type of review to be adopted by the committee (Table-3).

**Frequency of meetings**

It was revealed that 66.7% SOPs had mentioned that review committee will be seated 4 times a year to review the research proposals. Contrary to that 33.3% SOPs did not mention the frequency of the review meetings.

**Conflict of interest (COI) and voting power**

In the 77.7% SOPs there were clear indication that members will declare the COI before the Chairman of IECs in writing. However, only in 55.6% SOPs it was stated that there will be no voting power of members who had declared COI. Nothing was mentioned about voting power in decision making process in case of 44.4% SOPs.

**Decision making method**

It was revealed that majority 50% IECs adopted the board of consensus as decision making method while 7.1% stated that majority of votes will be taken in decision making.

**Continuing review and site monitoring**

In 22.2% SOPs it was stated that based on the level of risk involved the committee will be continuing review and site monitoring. On the other hand 44.4% IECs followed the frequency of continuing review as specified in the SOPs. We revealed that 33.3% IECs did not comment about continuing review and IECs monitoring in the SOPs.

**Record keeping and archiving**

It has been observed that majority 88.1% SOPs had stated about the record keeping and record archiving. There was no uniformity of record keeping duration. The record keeping time ranges between minimum 5 years to maximum 15 years.

**Administration and management**

In regard to IECs office administration and management it was found that 77.8% SOPs of IECs had mentioned that they kept provision of designated office space and staff. Similar percentage 77.8% had also budget provision to run the IEC activities.

**Registration and accreditation of IECs**

It was interesting to note that only 14.3% SOPs of North Eastern region were registered with the appropriate authority and due accreditation was given. However, among these only 50% renewed their registration.

**Discussion:**

**State wise status of IECs and SOPs**

An attempt was made to know the composition of IECs and prevailing status of SOPs of IECs in health research institutes of NE India.

We recorded that a majority 85.7% (12/14) of the health research institutes in NE India had constituted their IECs for biomedical research involving human participants and due notification was issued. Assam occupied the lowest position where 75 %( 6/8) health research institute had constituted their IECs. Similar findings were also observed in studies conducted earlier(6, 10, 11) where it was noticed that in spite of having guidelines many research institutes reportedly nonexistence of their own IEC or affiliation to any nearby institute. The non existence of IECs in health research institute in Assam may be explained mostly due to lake of trained manpower, lack of knowledge, interest/attention among the administrative heads and not having any legal frame work to constitute the IEC till the time of our study.

In regard to SOPs it was found that in NE region only 64.3% health research institutes had framed their own SOPs. Contrary to our findings study conducted by Sleem *et al*.,(12) in Egypt reportedthatmost (83.3%) of the surveyed research ethics committees had SOPs. In Assam and Tripura 50% health research institutes did not develop their SOPs. Earlier study conducted in African countries also made similar observation (13).

Without a written SOP the IECs may go after different methods of submission, approval and follow up of research (5). This eventually may result weak ethical review and monitoring. Hence, IECs may be unsuccessful to protect the dignity, rights, safety and well-being of research participants. Displaying of SOPs and IECs notification in institute website was not uniform. Overall in NE region it was 66.6% and lowest percentage was recorded in Assam and Tripura 50%. The web site display was 100% in Sikkim and Manipur. Notification of IEC and SOP is a non confidential document and is required to be made publicly available (websites) (14). However, it is yet to be implemented with letter and spirit in many of the health research institutes in NE region.

**Characteristics and Compositions of IECs and IEC members**

We evaluated the characteristics and compositions of the IECs among the available 12 number IECs and found that all the IECs were multi-disciplinary and multi-sartorial in nature as laid down in National Ethical Guidelines 2017 (1). Age and gender representation were up to the mark only in 66.7% and 58.3% ethics committees respectively. In a study conducted earlier 83% of health Research Ethics Committees showed less than half of the members were female (15). The sizes of the notified IECs were ranged between 7 to15. The balance between medical and non-medical/technical and non-technical members were not maintained in 50% IECs. According to a study conducted in Thailand the average number of committee members were 14 and the majority were scientific members (16). Similarly, Saito T (17) reported among Japanese Medical School ethics committees an inappropriate composition in majority of schools and recommended that more members from outside of the institute, younger members, and female reviewers should be added to the committee. Our findings indicate that either the health research institutes in NE region were not aware of the composition of IEC laid down in recent ICMR guideline 2017 (1) or poorly motivated to abide by the norms specified in the said guideline. On the other hand most Indian medical schools do not offer any recognized bioethics training during graduate and postgraduate courses and it is apparently difficult to get external members trained in Bioethics. There is more demand of professionals trained in Bioethics in India (5, 18).

It was imperative to note that in majority of the IECs the Chairmen were appointed from other than host institutes and their qualifications were in accordance with the ICMR guide line 2017(1). Contrary to our observation previous study conducted by Singh S in 2009 (10) found that only 74.1% IECs Chairmen were affiliated to host institutes. According to ICMR guideline non-affiliated EC members should be ≥ 50% in Ethic Committees. Dissimilar to this we recorded less than 50% non-affiliated members in 66.7% IECs. In our study all Member Secretaries (100%) and mostly Basic Medical Scientists (91.7%) and Clinicians (91.7%) were affiliated to host institutes. The Legal Experts of ethics committee were mostly non-affiliated to host institute. The qualifications of the Member Secretaries, Basic Medical Scientists, Clinicians and Legal Experts were found as per rules. It is noteworthy to mention that while constituting the IECs of health research institutes in NE region the ICMR guideline were conferred with. In 83.3% ethics committees Social Scientists/ Philosophers/ Theologians were present and they were mostly non affiliated (90%) to host institutes. However, their qualifications were not disclosed in the IECs notification/ SOPs. Appropriate constitution of IECs following national guidelines was also observed in earlier study (19). However, study conducted by ICMR in 2000 observed that there was no legal experts in most of the IECs and appointment procedures were questionable (7). To our revelation it was noted that 50% of the IECs did not have any lay persons. Earlier Nair and Martin stated that ‘Lay persons’ can be intimidated by the presence of more powerful scientific members (5). Representation of lay persons in IECs observed as significant weakness (19). Lack of lay person in IECs may be due to giving low importance or not considering the Lay persons as one of the essential member of the IECs as per schedule Y notification (8).

Quorum formation is one of the essential requirements of IEC meetings. It has been observed that the quorum requirement was not pointed out in 22.2% SOPs. This clearly substantiate that institutes have poorly considered the necessity of quorum formation. Therefore, the validity of ethics committee meeting was questionable which was held without quorum. The ICMR guideline 2017 stated that in each ethics committee meeting a minimum of five members should be present for quorum formation and the quorum should include both medical, non-medical or technical or/and non-technical members. Further minimum one non-affiliated member should be part of the quorum and preferably the Lay person (1, 7, 18).

Almost all IEC members were appointed by head of the institutes other than one where appointing authority was under secretary to the state government. The head of the institute should act as an appellate authority to appoint the committee members or to handle any disputes if arises (1).

The tenure of IECs abhorrently varies from 2-3 years in 55.6 % to more than 3 years in 22.2 %. The tenure was less than 2 years in 11.1% IECs. In general, the term of IEC membership may be 2–3 years. The duration could be extended on the basis of pattern mentioned in the SOPs. It is good to practice if a defined percentage of IEC members could be changed at a regular interval which will give opportunity to participate more people (1, 8, 19). Provision of honorarium to IEC members were explored and found that honorarium provision was made in 55.6% ethics committee only. Our finding is consistent with the findings of previous study (9, 10, 12). ICMR guideline 2017 advocates that IEC members may be given a reasonable honorarium for attending the ethics committee meetings (1). It will keep IEC members motivated and will be accountable to attend meetings.

In our study we observed that provision of training was specified only in 55.6 % SOPs. The poor training provisions were also found in several studied conducted previously (9, 10, 14, 18, 19). All IEC Members should undergo initial and continuing training in regard to research participant’s protection, IEC functions and SOPs. They should be well conversant with ethical guidelines, GCP guidelines (where applicable) and relevant regulations of the country (1, 7, 9, 18). Our study revealed that there is urgent need of training of IEC members in NE region of India.

Regarding role and responsibilities of IEC members we found that it was mentioned in 88.9 % SOPs. ICMR guideline stated that responsibilities of members should be clearly defined in the SPOs and it should be provided to IEC members at the time of their appointment (1).

**Submission procedure**

Evaluation of details of the documents to be submitted to the IECs along with the research proposal for ethical review revealed that 44.4% of IECs did not structured any check list to be used by the Principal Investigators. However, those IECs (55.6%) whoever framed their check list the contents were at par with the ICMR guideline (1). Similarly we noticed that the details of the documents to be included in the protocol were not mentioned in 22.2 % SOPs. Young and inexperienced researcher may find difficulty in absence of documents check list and details of documents to be included in protocol. Similarly the reviewer will lose their valuable time in absence of required documents need to be reviewed for protecting the dignity, rights, safety and well-being of the participants enrolled in the study.

**Review procedure and frequency of meetings**

Type of review varies from IEC to IEC and in 33.3% SOPs it was mentioned that all the three types of review will be adopted. However, it was not mentioned who will decide the type of review to be carried out and what will be the basis for deciding the review type. Differently in 55.6% SOPs it was stated that only two types of review namely full and expedited review will be implemented. It was interesting to note that in some of the SOPs nothing was mentioned about the type of review to be adopted by the IECs. ICMR guide line clearly stated that “The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize the research protocol into three types, namely, exemption from review, expedited review, and full committee review”(1). Strengthening of existing ethical review procedures carries paramount importance for laying a good foundation of ethical research (19).

Regarding frequency in most of the SOPs it was written that full committee will seat quarterly. However, in some SOPs frequency of full committee meetings not stated. Study conducted earlier revealed that the number of meetings ranged from 2-6 in a year or as per need (28%) (10). Thatte UM and Bavdekar SM stated infrequent meetings as one of the major ethical concerns (18). Unnecessary delay of research proposal approval/rejection may lead to withdrawal of research funding by the sponsor as well as reduce the probability of getting funding in future from the same sponsors and may increase the cost of research etc (20). Ideally IECs should meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed (1).

**Conflict of Interest (COI), voting power** and **decision making**

It is obligatory to declare or disclose the potential COI by researcher as well as if there is any among the members. If a member has declared COI then that should be submitted in writing to the Chairperson before the start of the meeting and it should be mentioned in the minute of the meeting. Members with COI should not take part in decision making process and preferably he should leave the room during the decision making of that particular proposal against whom COI was submitted (1). The ability of an impartial review of IEC is compromised in presence of members with conflicting interest (10, 19). In our study we found that there was clear statement in 77.7% SOPs that COI will be bought to the notice of the Chairperson of IEC in writing.

Surprisingly in regard to voting power only in 55.6% SPOs it was mentioned that there will be no voting power in decision making. In earlier study (16) a mixed observation was noted where in some IEC meetings members disclosed COI were requested to leave the IEC meeting room at the time of decision making and some were allowed to sit in the room but debarred to participate in casting vote. This may be explained that whoever were entrusted to draft the SOPs, either they were untrained or poorly motivated to refer the standard guide line during the drafting process of SOPs.

We observed that majority of the IECs had usedboard of consensus as decision making method while some of the IECs adopted majority of vote. Our findings were at par with the gold standard(1).

**Continuing review and site monitoring**

In small numbers of SOPs (22.2%) it was mentioned that continuing review and site monitoring will be decided on the basis of risk involved in the study. IECs members limit their responsibility for providing approval only to research proposals. Very little emphasis was given on the needs of continuing review and site monitoring(9, 18).

**Record keeping and archiving**

In our study in majority (88.9%) SOPs it was mentioned how long they will keep or archive the documents related to ethics committees review. However, the duration of record keeping varies from a minimum 5 years to maximum 15 years. Poor archiving and record keeping are the areas of concern connected to functioning of IECs (18). National ethical guideline 2017 reiterated that all documents and communication of IECs need to be dated, filed and preserved as per written procedures. Archiving of records must be for a period of 3 years after the completion of termination of the study. However, documents related to regulatory clinical trials must be archived for 5 years or as per regulations. IEC should express out the archival and retrieval mechanism in SOPs. All IEC records should be accessible for inspection by authorized representative of regulatory bodies. Wherever possible, electronic storage of record is encouraged in the guideline (1).

**Administration and management**

Provision of designated office space and staff were kept in more than 2/3rd (77.8%) IECs and similarly the budget were allocated. A survey of public sector teaching hospitals in Delhi conducted by Singh S, 2009 noted that adequate administrative support was present in 71 per cent IECs while inadequate financial support or absent was recorded in (43%) IECs (10).Other study conducted earlier showed that the effectiveness of research ethics committees in many countries is greatly restricted by lack of resources (21). National guideline (1) stated that all the IECs should have their own office space, independent staff and budget. Therefore, it may be mentioned that in NE region there is still scope to strengthen the administrative and management capacity of IECs by providing adequate infrastructure and keeping provision for budget. In this line advocacy need to be initiated with the implementing authority of NE states so as to have adequate administrative and management provision.

**Registration and accreditation of IECs**

To our surprise we found that most of the IECs of NE region were not registered under CDSCO and not accredited. Therefore, they were not eligible to conduct any regulatory trial. As per the Gazette notification of India, extraordinary part-II, no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with the licensing authority as defined in clause (b) of rule 21 (2). It is mandatory to renew the registration of IECs every three years to remain eligible to carry out clinical trials. However, very few were renewed their registration. This reflects the poor state of IECs currently available in NE region and regulatory trials are rarely being conducted.

**Conclusions:**

Our findings give us an insight that characteristics and compositions of many existing IECs of biomedical and heath research institutes in NE India are below par and not registered with the registering authority. Majority of the SOPs were not framed in reference to National Ethical Guideline for Biomedical Health Research, ICMR 2017. Therefore, it may be concluded that the mechanisms for ethical reviewing of research proposal involving human participates are weak and a cause of major ethical concern.

**Limitations of our study:**

The study was limited to only MCI recognised medical colleges of North Eastern Region and two of the Government of India health research institutes in Assam. IECs of private sectors were not part of this study. There was no MCI recognised Medical College in Nagaland and Mizoram at the time of our study. Therefore, these findings cannot be generalized to all IECs of this region. Moreover, two of the institutes had not constituted their IECs and three of the IECs had not framed their SOPs. As such, it is not coherent to comment about the profile of IECs and status of SOPs of these institutes.

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**Table-1 Characteristics and Compositions of IEC according to ICMR 2017 guideline (n=12\*)**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **Numbers** | **percentage** |
| Multi-disciplinary | 12 | 100 |
| Multi-sectoral | 12 | 100 |
| Adequate age representation | 8 | 66.7 |
| Adequate Gender representation | 7 | 58.3 |
| Non-affiliated IEC members | | |
| Number of committees having non-affiliated member  ≥50%  <50% | 4  8 | 33.3%  66.7% |
| Numbers of IEC members between 7 to 15 | 12 | 100 |
| Balance between Medical and non medical/technical and non technical members | 6 | 50 |
| Chairperson | | |
| Non affiliated Chairperson | 11 | 91.7 |
| Affiliated | 1 | 8.3 |
| No IEC constituted | 2 |  |

\*Excluded those institute who had not constituted their IECs

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

|  |  |  |  |
| --- | --- | --- | --- |
| SL No | Members of IEC/ Characteristics | Yes (%) | No (%) |
| 1 | **Chair Person** | | |
| * Non affiliated Chairperson | 11(91.7) | 1(8.3) |
| * Qualifications of Chairperson as per ICMR Guideline | 10(83.3%) | 2(16.7) |
| 2 | **Member Secretary** | | |
| * Affiliated | 12(100) | 0 |
| * Qualifications of as per ICMR Guideline | 12(100) | 0 |
| 3 | **Basic Medical Scientist** | | |
| * Affiliated | 11(91.7) | 1(8.3) |
| * Qualifications of as per ICMR Guideline | 12(100) | 0 |
| 4 | **Clinician** | | |
| * Affiliated | 11(91.7) | 1(8.3) |
| * Non affiliated |  |  |
| * Qualifications of as per ICMR Guideline | 12(100) | 0 |
| 5 | **Legal expert/s** | | |
| * Affiliated | 1(8.3) | 11(91.7) |
| * Non affiliated |  |  |
| * Qualifications as per ICMR Guideline | 12(100) | 0 |
| 6 | **Social Scientist/Philosopher/ethicist/theologan** | | |
| * Affiliated | 1(10) | 9(90) |
| * Not present | 2(16.6) |  |
| * Qualifications of as per ICMR Guideline |  |  |
| 7 | **Lay person(s)** | | |
| Status | No | Percentag |
| * Non affiliated | 6 | 50 |
| * No Layperson | 6 | 50 |
| Qualifications of as per ICMR Guideline | 3 | 25 |
| 8 | **Quorum requirements specified in SOPs as per ICMR guideline2017(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\*) \*excluded those who did not constituted IECs and had no SOPs | | |
| Tenure of IEC membership   * < 2 years * 2-3 years * >3 years * Not mentioned in SOP | 1  5  2  1 | 11.1  55.6  22.2  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 of 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 |

**Table-3: Submission and review procedure (n=9)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sl. No** | **Characteristics as per ICMR 2017 guideline** | **Frequency** | **Percentage (%)** |
| **1** | **Check list of documents to be submitted for IEC review** |  |  |
| * Check list present | 5 | 55.6 |
| * Check list absent | 4 | 44.4 |
| **2** | **Content of documents to be attached mentioned in the check list** | **Frequency** | **Percentage** |
| * Yes | 5 | 55.6 |
| * No | 4 | 44.4 |
| **3** | **Mention about details of documents to be included in the protocol** | **Frequency** | **Percentage** |
| * Yes | 7 | 77.8 |
| * No | 2 | 22.2 |
|  |  |  |
| **4** | **Types of review** | **Yes** | **Percentage** |
| * All three types | 3 | 33.3 |
| * Only two types | 5 | 55.6 |
| * None mentioned | 1 | 11.1 |
| Total | 14 | 100 |