**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 major 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. Majority 64.3% institutes had framed their SOPs. 21.4% IECs adopted all three types of reviews. 42.9% SOPs kept the provision of quarterly review meetings. Declarations of Conflict of Interest (COI) were specified in 50% SOPs. 35.7% SOPs mentioned about no voting power of members who declared COI. 57.1% 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**

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**INTRODUCTION**

Rapid changes in the era of globalised biomedical health research have added newer responsibility to researcher**s**, research conducting institute**s** and ethics committees. In this context appropriately constituted a functional research ethics committee has significant role to play in order to protect the dignity, rights, safety and well-being of research participants. It has always been necessary to review all types of biomedical and health research proposals involving human participants, their biological material and data (1). Therefore, each research institute is responsible for constituting an independent Institutional Ethics Committee (IEC) with the provision of logistic support in the form of staff, space, funds and protected time for member secretary(2). The ethical and scientific standards for conducting biomedical research on human subjects have been well laid down in the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (3) and the ICH Guidelines for Good Clinical Practice international guidelines, including the Nuremberg Code (4). The national ethical guideline for biomedical and health research involving human participants, ICMR 2017 have preserved that all types of biomedical and health research proposals must be reviewed by an IEC before it is conducted and should be regularly monitored the approved research to ensure ethical compliance throughout the conduct of research. Every research institute should have Standard Operating Procedure (SOP) and based on which the ethics committee (EC) should function to review the research proposal. The EC can refer the recently published ICMR guidelines in formulating such SOP for all biomedical and health research and to CDSCO guidelines for drug and device trials (**1).** It is also necessary to update the SOP time to time to incorporate the changes that have happened over time. In recent years there have been resentments among the public of being compromised the Responsible Conduct of Research by exploiting the potentially vulnerable research participants. The unethical behavior in scientific research is responsible for causing damage to public trust on researcher (2). Indian continent has been documenting several incidents of ethics dumping by social exploitation of the marginalized weaker, vulnerable research participants.Institutional mechanisms for ethical review of research involving human participants in India are weak and vulnerable (5). The supreme court of India has directed the CDSCO to get registered all the IEC who involve in regulatory research.North East India is more so and there is very limited trained manpower to conduct scientific and ethical review of research proposal submitted to EC. Insufficient ethics awareness usually observed on the part of the researcher in respect of responsible conduct of research. In many of the national and international journal do not have stringent rules to check or verify the publication ethics in research paper submitted for publication. Onus lies on the researcher to get the ethical approval from the concerned ethics committee. For obtaining ethical clearance in academic research are mere formalities. The licensing authorities have not made so far mandatory to register the ethics committee in case of non regulatory research. Even the regulatory bodies like MCI/CDSCO have little or no control over IEC in academic medical institute for non regulatory research. In recent time, it has been made mandatory to include research publications as one of the criteria in promoting teachers working in medical colleges of India. However, no criteria laid down for the quality of research publications and no means developed to verify the authenticity of ethical approval prior to the study conducted. All these led to compromise responsible conduct of research.

The success of the protection of research participants mostly depends on the existence of appropriately constituted capable EC and independence to deal with ethics review (6). In view of the above, it has been felt that it is necessary to understand the status of IEC of health research institute specifically academic institute of public and private sector of NE states, India who involved mostly in academic research and moderately in regulatory research.

**Objectives:**

To assess the composition of Institutional Ethics Committees (IEC) Human and status of Standard Operating Procedure (SOP) of IECs in health research institutes of North East India

**Methods**

**Study Design:**

A cross-sectional institutional based observational study was conducted over a period of 6 months in 2018. In this study 14 Institutional Ethics Committees (Human) of MCI recognised Medical Colleges and one Research Institute located in North East India were incorporated. A questionnaire was develop and validated. Study materials used were latest notification of IEC and SOPs of respective Medical College/Research Institute. The information collected were composition of IECs, affiliation and qualification of EC members, review procedures and records keeping, financial and material status. The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants of ICMR, 2017 was taken as gold standard for comparison of our findings. In order to simplify the study and to minimise error, we have specified the inclusion criteria that the IEC (H) willing to provide latest IEC Notification and or SOP of Institutional Ethics Committee (H) or if the said materials are available in their institute website for public use.

**Data collection procedure**: An attempt was made to collect the latest notification of IECs and SOPs from MCI recognized Medical Colleges and Health research institutes of NE Region of India through Email/Personal Contact /Telephone etc. Additional effort was also made to download the SOP of IEC from the respective institutions web site if made available in public domain. Desk evaluation was done of the collected EC notifications and SOPs. Tabulated results were compared during discussion with the ICMR-IEC guideline 2017 as a gold standard. Strict confidentiality was maintained while handling the dataset and Institute names were delinked while analyzing the data.

**Data analysis:** 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 Institutional Ethics Committee (H), Jorhat Medical College, Jorhat, Assam

**Results**

**State and facility type of IECs**

In the present study we enrolled 14 (Fourteen) Institutional Ethics committees (Human) from North East (NE) India. Of these 14 IECs 12 were Medical Council of India (MCI) recognized Medical Colleges, one Health Research Institute from ICMR under Ministry of Health and Family Welfare and one from Air Force Hospital under Aviation Ministry of Govt. of India. Of these IEC 57.1% was from Assam, 14.2% from Manipur and Tripura each while Meghalaya and Sikkim had only 7.1% each.

**State wise Status of IECs and SOPs**

It has been revealed that of the 14 health research institutes only 12 (85.7%) had constituted their IEC (H). Assam was the one state where no IEC (H) was constituted in two of the institutes. Of them one was belong to Central Government Institute and another one was Medical College under the state Government of Assam. Rests of the institute have constituted their own IEC (H) and it was notified (Table-1).

**Table 1: State wise Status of IECs and SOPs**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| State | No of EC | EC constituted (%) | No of EC having SOP (%) | Percentage | SOP displayed in Institute website (%) (N=9) |
| Assam | 8 | 6 (75%) | 4(50%) | 50% | 2(25%) |
| Manipur | 2 | 2(100%) | 2(100%) | 100% | 1(50%) |
| Meghalaya | 1 | 1(100%) | 1(100%) | 100% | 1(100%) |
| Tripura | 2 | 2(100%) | 1(50%) | 50% | 1(50%) |
| Sikkim | 1 | 1(100%) | 1(100%) | 100% | 1(100%) |
| Total | 14 | 12(85.7%) | 9(64.3%) | 64.3% | 6 (66.6%) |

As far as Standard Operating Procedure (SOP) is concerned it was found that only 64.3% institutes in North Eastern region had developed their SOP. State wise availability of SOP confirmed that in Assam and Tripura 50% institute had framed their own SOP. While in Manipur, Meghalaya and Sikkim had SOP (100%) in all their research institutions.

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 web site 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 IEC**

We evaluated the characteristics of the IEC among the available IECs (12) and found that all the Ethics Committees 100% were multi-disciplinary and multi-sectorial in nature. Adequate age representations were seen in 66.7% while adequate gender representations were seen only in 58.3% of the ethics committees (Table-2).

**Table 2 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 EC members | | |
| Number of committees having non-affiliated member  ≥50%  <50% | 4  8 | 33.3%  66.7% |
| Numbers of EC members between 7 to 15 | 12 | 100 |
| Balance between Medical and nonmedical/technical and non technical members | 6 | 50 |
| Chairperson | | |
| Non affiliated Chairperson | 11 | 91.7 |
| Affiliated | 1 | 8.3 |
| No IEC constituted | 2 |  |

According to ICMR guideline 2017, preferably 50% of the members of the ethics committees should be non-affiliated or from outside the institution. However, our study revealed that 66.7% ethics committees have less than 50% non-affiliated members. In all the notified IECs (100%) numbers of Ethics Committee members were in between 7 to 15. The Balance between medical and non-medical/technical and non technical members were seen in 50% of the available ethics committees.

**Affiliation, qualification of EC members**

In regard to non affiliation of Chairpersons it was found that majority 91.7% Ethics committees had non-affiliated Chairpersons and 83.3% Chairpersons qualifications were found at par with the ICMR guide line 2017.

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 ethics committee 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% ethics committees. Among these 90% were non-affiliated. The qualifications of these members were mentioned neither in the EC 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 ethics committees without having any Lay persons.

We enquired the Quorum requirements assessment as specified in ICMR guideline2017 and found that 58.3% had specifically mentioned the requirement of quorum in the respective SOPs. Contrary to this 16.7% did not mention the requirement of quorum while the status of quorum requirements in 25% were not know as they had no SOPs.

It has been observed that in 91.7% ethics committees 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 35.7% IECs the term of the committee was 2-3 years. While the term was less than 2 years in 7.1% and more than 3 years in 14.3% Ethics committees. The tenure of Ethics committee was not mentioned in 7.1% SOPs. We could not ascertain the tenure in case of 35.7% institute as there was no Ethics committees or SOPs.

Provisions of Honorarium to EC members for attending meeting were evaluated and it was found that provisions of honorarium were kept only in 35.7% IECs. There was no mention about Honorarium provisions in 14.3% SOPs and provisions not kept in 14.3% IECs.

Provision of Training of EC members specified in 35.7% SOPs. Conversely 28.6% SOPs did not mention about the training provisions for ethics committee members. Roles and responsibilities of EC members defined in 57.1% SOPs. While no mentioned were seen in 7.1% SOPs (Table-3).

**Table 3 Affiliation, qualification of EC members (n=12)**

|  |  |  |  |
| --- | --- | --- | --- |
| SL No | Members of EC/ 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 |
|  | Affiliated | 0 |  |
|  | Non affiliated | 6 | 50 |
|  | No Layperson | 6 | 50 |
|  | Qualifications of as per ICMR Guideline | 3 | 25 |
| 8 | Quorum requirements specified as per ICMR guideline2017 | | |
|  | yes | 7(58.3) | 2(16.7) |
|  | Not known | 3(25) |  |
| 9 | Terms of references for EC members | | |
| Selection/appointment process to committees (n=12) | | | |
|  | * Appointed by Head of the institute | 11(91.7) | 1(8.3) |
|  | * Others | 0 | 0 |
| Term of EC membership (n=14) | | | |
|  | Tenure of EC membership  < 2 years   * 1. years   > 3 years  Not mentioned in SOP  No SOP(No EC\_2+No SOP\_3) | 1  5  2  1  5 | 7.1  35.7  14.3  7.1  35.7 |
|  | Honorrium(n=14) | | |
|  | Provision of Honorarium to EC member for attending meeting | Numbers | Percentage |
|  | Yes | 5 | 35.7 |
|  | No provision of honorarium | 2 | 14.3 |
|  | Not mentioned in SOP | 2 | 14.3 |
|  | Not known as SOP not available | 3 | 21.4 |
|  | No IEC | 2 | 14.3 |
| 10 | Training (n=14) | | |
|  | Provision of Training of EC members specified in SOP |  |  |
|  | Yes | 5 | 35.7 |
|  | Not mentioned in SOP | 4 | 28.6 |
|  | Not known as no SOP | 3 | 21.4 |
|  | No IEC | 2 | 14.3 |
| 11 | Roles and responsibilities (n=14) | | |
|  | Roles and responsibilities of EC members defined in SOP |  |  |
|  | Yes | 8 | 57.1 |
|  | No | 1 | 7.1 |
|  | NO SOP | 5 | 35.7 |

**Submission procedure**

Mention about details of documents to be submitted for IEC review were explored. It was observed that only 35.7% ethics committees had their own check list to be used by the researcher while submitting research proposal to ethics committees. The contents of the check lists were 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 50% SOPs (Table-4).

**Review procedure adopted**

In regard to type of review procedure of the ECs it was found that 21.4% IECs adopted all the three types of review namely full review, expedited review and exemption from review. On the other hand 35.7% SOPs it was mentioned that only two type of review will be adopted (Full review and Expedited review). To our surprise 7.1% SOPs of IECs did not mention the type of review to be adopted by the committee (Table-4).

**Table 4: Submission and review procedure (n=14)**

|  |  |  |  |
| --- | --- | --- | --- |
| Sl No | Characteristics as per ICMR 2017 guideline | Frequency | Percentage (%) |
| 1 | **Check list of documents to be submitted for EC review** |  |  |
|  | Check list present | 5 | 35.7 |
|  | Check list absent | 4 | 28.6 |
|  | Not known as no IEC/SOP | 2 | 14.3 |
|  | No information as no SOP | 3 | 21.4 |
| 2 | **Content of documents to be attached mentioned in the check list** | **Frequency** | **Percentage** |
|  | * Yes | 5 | 35.7 |
|  | * No | 4 | 28.6 |
|  | * Not known as no IEC/SOP | 5 | 35.7 |
| 3 | **Mention about details of documents to be included in the protocol** | **Frequency** | **Percentage** |
|  | * Yes | 7 | 50 |
|  | * NO | 2 | 14.3 |
|  | * Not known as no IEC/SOP | 5 | 35.7 |
|  |  |  |  |
| 4 | **Types of review** | **Yes** | **Percentage** |
|  | * + **All three types** | 3 | 21.4 |
|  | * **Only two types** | 5 | 35.7 |
|  | * + **None mentioned** | 1 | 7.01 |
|  | * Not known as no IEC/SOP | 5 | 35.7 |
|  | Total | 14 | 100 |

**Frequency of meeting**

It was revealed that 42.95% SOPs had mentioned that review committee will be seated 4 times a year to review the research proposals. Contrary to that 21.4% SOPs did not mention the frequency of the review meetings. We could not ascertain the status for 35.7% study institutes as there was no SOP or IEC.

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

In the 50% SOPs there were clear indication that members will declare the COI before the Chairman of IECs in writing. However, only in 35.7% SOPs it was stated that there will be no Voting Power of Members who had declared COI. Nothing was mentioned about COI and Voting Power in decision making process in case of 28.6% SOPs.

**Decision making method**

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

**Continuing review and site monitoring**

In 14.3% 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 28.6% IECs followed the frequency of continuing review as specified in the SOPs. We revealed that 21.4% IECs did not comment about continuing review and ECs monitoring in the SOPs.

**Record keeping and archiving**

It has been observed that only 57.1% 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 57.1% SOPs of IECs had mentioned that they kept provision of designated office space and staff. Similar percentage 57.1% had also budget provision to run the ECs activities.

**Registration and accreditation of ECs**

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**

An attempt was made to know the composition of IEC and prevailing status of Standard Operating Procedure (SOP) of Institutional Ethics Committee(S) in health research institutes of North East India. All possible efforts were made to collect the notification of IECs and SOPs through email from the Institution Head or Member Secretary or through the Faculty members working in respective institute. An effort was also made to download the notification of IEC and SOPs from the respective institute web site if the same have been made available in public domain. We found that there were 14 IEC in health research institutes of North East region. Among them 13 were in Government institutions and one in private institute. Of these institutions 12 were Medical colleges, one Regional Medical Research Centre under ICMR and another one Air Force Hospital under Aviation Ministry. State wise location of IECs revealed that majority 8 IECs were from Assam, 4(four) were from Manipur and Tripura, 1(one) from Meghalaya and another 1(One) from the state of Sikkim.

**State wise Status of IEC and SOP**

In our study we recorded that 85.5% of the health research institutes in NE India had constituted their IEC for human research and due notification was issued. To our surprise two (25%) of the institutes of Assam had not constituted the IEC. Of these one was Medical College under state Government and one hospital cum teaching institute under Government of India. Rest of the States had constituted their IECs and notification was made available.

Similar findings were also observed in study conducted earlier(1, 7**)** that two of nine (22%) hospitals reported absence of their own IEC or affiliation to any nearby institute. The non existence of IECs in health research institute may be explained mostly due to lake of trained manpower, lack of 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 (3) 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 observat.ion (8). Our observation reflected that the institutes were not giving due focus to protect the dignity, rights, safety and well-being of research participants. Displaying of SOPs and IECs notification was not uniform. Overall in NE region it was 66.6% and lowest percentage was recorded in Assam 25% while in Manipur and Tripura it was 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 (Internet/website) **(9).** However, it is yet to be implemented with letter and spirit in many of the health research institute in NE region.

**Characteristics and Compositions**

We evaluated the characteristics and composition of the IEC among the available 12 number IECs and found that all the ethics Committees were multi-disciplinary and multi-sartorial in nature as laid down in National Ethical Guidelines 2017 (2).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 (4).According to ICMR guideline non-affiliated EC members should be ≥ 50% in Ethic Committees. Contrary to this we recorded less than 50% non-affiliated members in 66.7% ECs. The sizes of the notified EC were ranged between 7to15. The balance between and nonmedical/technical and non technical members were not maintained in 50% ECs. According to a study conducted in Thailand the average number of committee members were 14 and the majority were scientific members(10).Similarly,Saito T et al (11)reported among Japanese Medical schools ethics committees an inappropriate composition of the committee in the 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 institute in NE region were not aware of the composition of Ethics committee laid down in recent ICMR guideline 2017 (2)or poorly motivated to abide by the norms specified in the said guideline.

**Affiliation, qualification of EC members:**

It was imperative to note that in majority of the ECs the Chairmen were appointed from other than host institutes and their qualifications were [in accordance with](https://www.bing.com/search?q=define+in+accordance+with) the ICMR guide line 2017. Contrary to our observation previous study conducted by Singh S in 2009 (1) found that only 74.1% ECs Chairmen were affiliated to host institutes. In our study all Member Secretaries and mostly Basic Medical Scientist (91.7%) and Clinicians (91.7%) were affiliated to host institutes. On the contrary Legal Experts of ethics committee were non-affiliated to host institute. The qualifications of the Member Secretary, Basic Medical Scientist, Clinicians and Legal Experts were found as per rules. It is noteworthy to mention that while constituting the Institutional Ethics Committees in NE region the ICMR guideline were conferred with. In 83.3% ethics committees Social Scientist/ Philosopher/ Theologians were present and they were mostly non affiliated (90%) to host institutes. However their qualifications were not disclosed in the EC notification/ SOPs. To our revelation it was noted that 50% of the ECs did not have any lay persons and this may be due to giving low importance or not considering the Lay persons as one of the essential member of the ECs. Earlier Radhika Brahme and Sanjay Mehendale observed thatmajority of the institutions constituted their ECs by selecting members from various fields (12).

Quorum formation is one of the essential requirements of ECs meeting. It has been observed that the quorum requirement was pointed out only in 58.3% 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 each in 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 (2).

Almost all EC members were appointed by head of the institutions 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 (2).

The tenure of ECs abhorrently varies from 2-3 years in 35.7% to more than 3 years in 14.3%. The tenure was less than 2 years in 7.1% ECs. In general, the term of EC 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 EC members could be changed at a regular interval (**2).** Provision of honorarium to EC members were explored and found that honorarium provision was made in 35.7% ethics committee only. Our finding is consistent with the finding of previous study. (1, 3) ICMR guideline 2017 advocates that EC members may be given a reasonable honorarium for attending the EC meetings (2). It will keep EC members motivated and will be accountable to attend EC meetings.

In our study we observed that provision of training was specified only in 35.7% SOPs. The poor training provisions were also found in several studied conducted previously (1, 5, 9). All EC Members should undergo initial and continuing training in regard to human research protection, EC functions and SOPs. They should be well conversant with ethical guidelines, GCP guidelines (where applicable) and relevant regulations of the country (2). Our study revealed that there is urgent need of training of EC members in NE region.

Regarding role and responsibilities of EC members we found that nothing was mentioned in 42.9% SOPs. ICMR guideline stated that responsibilities of members should be clearly defined in the SPOs and it should be provided to EC members at the time of their appointment. The non compliance may be due to poor consultation of the ICMR guideline while framing the SOPs of ECs.

**Submission procedure:**

Evaluation of Details of the documents to be submitted to the IECs along with the research proposal for ethical review revealed that majority of ECs did not structured any check list to be used by the Principal Investigators. However those ECs who framed their check list the contents were at par with the ICMR guideline (2). Similarly we noticed that the details of the documents to be included in the protocol were mentioned only in 50% 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 adopted:**

Type of review varies from EC to EC and in 21.5% SOPs it was mentioned that all the three type 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 35.7% 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 ECs. 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”(2).

**Features of Full committee review**

Frequency: In most of the SOPs it was written that full committee will seat quarterly. However in some SOPs frequency of full committee meeting not stated. Earlier study conducted revealed that the number of meetings ranged from 2-6 in a year or as per need (28%) (1). Ideally EC 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 (2).

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

It is obligatory to declare or disclose the potential Conflict of Interest 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 (2).In our study we found that there was clear statement in 50% SOPs that COI will be bought to the notice of the Chairperson of EC in writing. Surprisingly in regard to voting power only in 35.7% SPOs it was mentioned that there will be no voting power in decision making. In earlier study a mixed observation was noted where in some EC meetings members disclosed COI were requested to leave the EC 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.

**Decision making method**

We observed that majority of the ECs had usedboard of consensus as decision making method while some of the ECs adopted majority of vote. Our findings were at par with the gold standard(2).

**Continuing review and site monitoring**

It was mentioned in the 14.3% SOPs about continuing review and site monitoring which will be decided on the basis of risk involved in the study. It indicates that very little emphasis was given on the needs of continuing review and site monitoring. We found that most of the ECs of NE regions were not registered under CDSCO. Therefore they were not eligible to conduct regulatory trial. To our surprise even the Prime research organization of Government of India located in NE region was not found to be eligible to conduct regulatory trial because of not being registered with regulatory authority. As per the Gazette 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 (12).

**Record keeping and archiving**

In regard to record keeping and archiving we found that in majority (57.1%) 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 EC to EC with a minimum 5 years to maximum 15 years. National ethical guideline 2017(2) reiterated that all documents and communication of ECs need to be dated, filed and preserved as per 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. EC should express out the archival and retrieval mechanism in SOPs. All EC records should be accessible for inspection by authorized representative of regulatory bodies. Wherever possible, electronic storage of record is encouraged in the guideline.

**Administration and management**

Provision of designated office space and staff were kept in more than half of the (57.1%) ECs 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 (1).Other study conducted earlier showed thatthe effectiveness of RECs in many countries is greatly restricted by lack of resources (13).National guideline (2) stated that all the ECs should have their own office space, independent staff and budget. Therefore, it may be mentioned that in NE region there is still much scope left to strengthen the administrative and management capacity of ECs 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 ECs**

We recorded a very poor numbers of Health Research Institute who had registered their ECs with the regulatory authority and due accreditation was given to them. It is mandatory to renew the registration of ECs every three years to remain eligible to carry out clinical trial However, very few were renewed their registration. This reflects the poor state of ECs currently available in NE region and therefore regulatory trials are rarely being conducted in this region.

**Conclusions**

Our study revealed that majority of the heath research institutes had their independent IECs. However, many of the IECs had not developed their SOPs as per recommendation of ICMR guideline 2017. To our surprise very few numbers of IECs were registered and accredited in North East India. Therefore it may be recommended to organize a participatory capacity building training involving all the health research institutes of North East India.

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