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EVALUATION OF ERRORS AND COMPLETENESS OF RESEARCH APPLICATION FORMS SUBMITTED TO THE INSTITUTIONAL ETHICS COMMITTEE (IEC) OF A TERTIARY CARE INSTITUTION: AN OBSERVATIONAL STUDY

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ABSTRACT: **Introduction:** IECs seek a duly filled application form to provide the overview of the study as per ICMR guidelines in the process of review and to maintain study related records. **Aim and Objectives:** To evaluate the errors and completeness of research application forms submitted to IEC. **Materials and Methods:** The present study was undertaken after obtaining approval from IEC, GMC, Kathua. Application forms from January 2023 to December 2024 were analysed regarding: Type of studies, study duration and design, title, detail and signature of investigators, informed consent process, involvement of the vulnerable population, declaration of conflict of interest. **Results:** Total 43 application forms were analysed in which details of principal & co-investigators were incomplete in 19 (44.18%), duration of study was not mentioned in 18 (41.18%), consent forms were missing in 17 (39.5%) forms. The signatures of the head of department and investigators were missing in 14 (32.5%) and 11 (25.58%) forms respectively. All forms mentioned complete title, aims & objectives, background and specified about DCGI permission. **Conclusion:** Current study underlines that majority of application forms (52%) were incomplete and had one or more errors. This underscores the need of periodic meetings of IEC and awareness among researchers.

INTRODUCTION: It is mandatory to get approval from the Institutional Ethics Committee (IEC) before conducting any biomedical research project. One of the necessary documents which needs to be submitted to the IEC along with the research proposal is the Application form. A duly filled and well-designed application form provides a summary of the whole project which expedites the review process by the ethics committee¹⁻³. All IECs in India have their own format of application form designed according to the standard operating procedures (SOPs) and requirements stated in the ICMR guidelines 2017.

These SOPs should be updated and improved regularly based on the continuously changing requirements and criteria as this will eventually enhance the quality of research in India. IEC members should conduct regular meetings and provide valuable inputs to the researchers regarding the welfare and safety of the research participants in order to ensure and maintain the scientific soundness and credibility of the proposed research.

Conducting periodic reviews of the research study, checking the submitted application forms, maintaining confidentiality of records, ensuring safety of the subjects and following all principles of bioethics is the main responsibility of the ethics committee⁴. The guidelines of World Health Organization (WHO) and Indian Council of Medical Research (ICMR) recommend that all necessary documents should be submitted along with the application form to the Ethics committee. It becomes a lot tedious and time consuming for the

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ethics committee if the application forms are not completely filled or wrongly filled, ultimately adding up the burden on the members of the ethics committee. This becomes a big hurdle in understanding the review process and giving clearance to project ^{5, 6}. Moreover, getting ethical clearance for multicentric studies becomes more cumbersome as the requirement is different for Independent and Institutional Ethics Committee (IEC) ⁷. Therefore, it is very important to submit a duly filled application form to the ethics committee. Further, there is a paucity of studies done to assess the completeness of the application forms to the ethics committee. Hence, the present retrospective observational study was planned to check the completeness of and to find errors in application forms submitted to ethics committee of our institution.

MATERIALS AND METHODS: The present study was conducted after obtaining approval from Institutional ethics committee vide no. IEC/GMCK/2024-25/158 dated 30/12/2024. All principles of bioethics were followed. The application forms of all research projects submitted to the IEC of Government Medical College, Kathua from January 2023 to December 2024 were assessed for completeness and errors. The application forms submitted were evaluated for the following parameters: type of the study, detail of the study investigators, study participants, title of the study, signature of all investigators, mention of the duration of study, regulatory approval, informed consent form, information about sponsor, declaration of conflict of interest, permission obtained from the head of department, place of study and involvement of the vulnerable population. Comparison was also done among the research proposals submitted by the undergraduates and faculty/ postgraduates.

RESULTS: A total of 43 application forms of research studies submitted to the IEC of Government Medical College, Kathua from January 2023 to December 2024 were evaluated. Out of these, 40 were research studies and 3 were dissertation studies **Table 1**. The 40 research studies comprised of 38 observational and only 2 interventional studies. Most of the application forms (34) were submitted in 2024 and only 9 were submitted in 2023.

27 out of 43 studies were prospective in the submitted application forms, followed by 7 cross sectional and 6 retrospective studies. A total of 3 application forms were either wrongly mentioned or did not mention the type of study **Table 4**. Majority of the studies were submitted by residents and faculty (39). Details of the principal & co-investigators were incomplete in 19 (44.18%) application forms. The expected duration of study was not specified in 18 (41.18%) application forms. 17 (39.5%) application forms required attachment of informed consent form but failed to attach it alongside, whereas only 10 application forms were submitted along with attached consent forms.

The signature of the head of the department concerned was missing in 14 (32.5%) study proposals. 11 (25.58%) application forms were submitted without the sign of investigators. 9 (20.9%) application forms were submitted without any mention of the vulnerable population involved in the research project. Details on conflict of interest in the study was missing in 6 (13.9%) application forms, where as 4 (9.3%) study proposals submitted for approval did not provide any information regarding the source of funding involved in carrying out the study. Only 1 application form was having incomplete study design (2.3%) **Table 3**.

However, all the application forms submitted to the ethics committee mentioned the complete title of the study, aims & objectives of study, background of the study and specified that permission from DCGI was not required for the particular study. Also, all the studies were carried out at our institute only **Table 2**.

TABLE 1: DISTRIBUTION OF TYPES OF STUDIES

Type of Study Mentioned in Application form	
Type of study	Number
Dissertation	3
Research study	40
Observational	38
Interventional	2

TABLE 2: COMMON ELEMENTS

Points Mentioned In All Application Forms
Title was completely write
Name of centre involved
Aims and Objectives
Background of study
Mentioned that permission from DCGI was not required

TABLE 3: SUMMARY OF DISCREPANCIES AND MISSING INFORMATION IN RESEARCH APPLICATION FORMS BY TYPE OF SUBMITTER

Points not Mentioned in Application Forms			
Discrepancy in different parameters assessed	Total (%)	Faculty & Residents	Undergraduates
Details of Principal & Co-Investigator	19 (44.18%)	15	4
Detail of funding agency	4 (9.3%)	2	2
Study design was incomplete	1 (2.3%)	1	0
No mention of vulnerable population	9 (20.9%)	7	2
No mention of ethical issues	6 (13.9%)	5	1
No mention of cost involved	4 (9.3%)	3	1
Consent forms not attached	17 (39.5%)	16	1
Conflict of interest not mentioned	6 (13.9%)	2	4
Not forwarded by Head of department	14 (32.5%)	14	0
Not signed by investigator	11 (25.58%)	11	0
Study duration not mentioned	18 (41.8%)	16	2

TABLE 4: YEAR-WISE COMPARISON OF TYPES OF STUDIES MENTIONED IN APPLICATION FORMS SUBMITTED IN 2023 AND 2024

Year wise comparison (2023-2024) with regard to type of study mentioned		
Type of study	2023	2024
Retrospective	0	6
Prospective	6	21
Cross sectional	0	7
Type of study not mentioned	2	0
Type of study wrongly mentioned	1	0

DISCUSSION: Ethics review is mandatory for projects involving human subjects to protect the rights and safety of research participants. The responsibility of IEC is to maintain the quality, authenticity and validity of reviews of the research proposals⁸. The ethics committees adhere to the guidelines recommended by ICMR and the WHO Guidelines which govern the committees review process with the goal of safeguarding the dignity, rights, safety of every human subject participating in the trial and protecting the ethical principles of autonomy, non-malificence, beneficence and justice in accordance with Good Clinical Practice guidelines³. Incompleteness of the application form delays the review process, and this can create conflict between the IEC members and the researchers⁹.

The present study was carried out to evaluate and check the submitted application forms according to the standard operating guidelines of ICMR 2017 & WHO Guidelines.

Very less studies were found similar to this study when we reviewed the literature¹⁰. However the applications form submitted by the researchers had various deficiencies regarding information about conflict of interest, informed consent forms, involvement of vulnerable population, mention of

ethical issues, mention of cost involved, detail of funding agency, detail of investigators, mention of study duration. This indicates lack of proper training in research methodologies resulting in lack of knowledge about filling of the application forms.

In the present study, there were 11 application forms which were not signed by the investigators and 14 applications were submitted without permission from the head of the department. It is essential to mention that these discrepancies were found at the level of residents and faculty of our institution, rather than undergraduates who submitted the signed and forwarded application forms. Most of the application forms were submitted by residents and faculty than undergraduates which implies lack of awareness among the undergraduate medical students of this institution regarding conduct of scientific research studies.

Our results were different from a similar study conducted by Sheety *et al*, in which the positive findings were that the researchers were well aware of informed consent process, confidentiality statement, statement related to right to withdraw, statement related to compensation of participation, purpose and procedures of the study and provided complete details regarding the same¹¹. Similar

study was undertaken by Shah PC *et al* in which the common discrepancies found were related to title of studies, information about collaborating centers, type of studies, project budget and compensation related issue¹². The IEC can hold workshops for training the researchers at undergraduate as well as faculty level. There should be a uniform and same application form for all the Ethics committees which needs to be made available online by the national regulatory authority¹³.

The positive factor in this study is that all the researchers provided complete details of the title of study, name of the centre involved, aims and objectives, background of the study and mentioned that permission from DCGI is not required for carrying out their study.

CONCLUSION: 21 (48%) submitted proposals had no error and were complete in all aspects. However, in 22 application forms (52%), errors were detected. The number of errors were more than one in most of research proposals submitted to the IEC. The current study highlights the importance of updating the investigators regarding submission of application forms and periodical meetings of ethics committee which will expedite the speed and improve the quality of review process.

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