ORIGINAL ARTICLE

COMPLETENESS OF INSTITUTIONAL ETHICS APPLICATION FORMS SUBMITTED TO THE ETHICS COMMITTEE IN A RURAL TERTIARY TEACHING HOSPITAL

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ABSTRACT

Aim & objective: To evaluate the completeness of ethics application forms submitted for review to institutional ethics committee.

Materials & methods: Application forms of year 2011-2013 submitted to our institutional ethics committee were studied.

Results: The total numbers of application forms submitted to ethics committee were 100. Of these 67 were dissertation and 33 were research project. The type of studies consists of observational prospective studies (88%), procedure related studies (8%) & interventional studies consist of clinical trial (4%). Title of study was incomplete in 15 forms and place of the study was not mentioned in 11 forms. Time period required was mentioned in 76 forms. Only 37 forms have attached the consent form. Involvement of risk to participating subjects mention in 7 forms, none of form filled information related to compensation, financial burden will be met and conflict of interest and data maintence and storage of application forms.

Conclusion: The present study highlights the importance of knowledge and awareness about the filling of the application forms of ethics committee. A uniform well prepared application form of ethics committee required for evaluation and understanding of research project.

Keywords: Application form, Institutional Ethics Committee, Standard Operating Procedure.

INTRODUCTION

The most important & first step to carry out study or research is to design the protocol & get ethical approval from ethics committee. Permission of ethics committee is taken through the application form. The complete information in the application form not only results in well planning of study by the investigators but also helps to member of ethics committee to understand study in short period of time & for assessment, analyzing the research project. It is also important to keep & maintain the records of study and research over a period of time. Failure of mentioning important points lead to difficulty in understanding as well as giving permission for approval of the study.

The Indian council of medical research (ICMR) New Delhi 2006[1], World Health Organization (WHO)[2] recommends the formation of Ethical Review Committees (ERCs) at the Regional, National and Institutional level and had provided operational guidelines for ERCs.

Institutional Ethics Committee (IEC) is an independent body whose responsibility is to ensure the protection of the rights, safety, dignity and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection. IEC will be multidisciplinary and multi-sectorial in composition. It will comprise of active members who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests.[3]

The ideal application form should include all information regarding study plan procedure, regulatory, permission, financial, ethical aspects of study. The checklist of compulsory mandatory documents should be enclosed with the application form when a study proposal is submitted to the ethics review committee.

After analysis & review of the study application form by members of the ethics committee, the committee gives a decision regarding the approval of study. Failure of mentioning important details in application form leads to difficulty in understanding study design further prolongation of procedure.

Requirement of ethics review forms of studies submitted to ethics committee vary from one ethics committee to other. To have a uniform requirement about filling the application form of ethics committee there was need of increasing awareness and knowledge among the investigators & committee members of IEC. It essential to check completeness of application form of institutional ethics committee, hence the present study was carried out to evaluate the completeness of application forms submitted to our institutional ethics committee.

MATERIALS AND METHODS

This was retrospective observational study carried out at our rural tertiary teaching care hospital. Total 100 application forms of year June 2011 to December 2013 were analyzed for their completeness. The parameter evaluated were: Total number of studies, type of study, filling of application forms containing - title of study, name & signature of principle & co-investigator, permission obtained from the head of department, other department that are involved, place of study, risk factor related with the study & patients, involvement of vulnerable population, consent of patient, conflict of interest, sponsoring authority for the study, data maintence and record keeping of application forms.

RESULTS

The results of study were obtained after analyzing the parameters with use of Microsoft office Excel 2007 sheet.

a) Number of studies submitted to the ethics committee: There were a total number of 100 studies evaluated of which 67 were dissertation studies & 33 were research projects.

b) Type of studies submitted to the ethics committee: A total 100 studies were submitted to IEC consist of 88 observational epidemiological studies, 8 were procedural related, 4 were interventional studies consist of four clinical trials, only one of which is initiated.

c) The title of study: Title was incomplete in respect to use of the short forms which was complete in 85 forms and incomplete in 15 forms.

d) Permission aspect: Name and signature of primary & co-investigators were present in all application forms. Permission of other department was required in 27 studies out of 100. Of these 22 forms mention the permission by including name and signature of head of relevant department along with stamp remaining 5 studies form does not mention about the permission of other departments. The permission from the head of concerned department and the head of institute was sought in all the study proposal.

e) Place of study to carried out: Most of studies (90) were carried out at our institute however 10 studies fails to mention the location of study.

f) Study duration: The expected duration required to complete study was mentioned in 76 forms & fails to mention in 24 forms.

g) Patient safety factors: Involvement of risk of study or procedure, adverse drug reaction, measures to counteract the risk factor to the patient were mentioned only in 7 patients out of which 3 of them mention the actual risk to the patient. None of the application form gives information related to about compensation given due to the risk involvement.

h) Details about the research project: The application form submitted to our ethics committee included objectives of study (100%), current knowledge about research subject (92%), research plan protocol (90%).

i) Conflict of interest & sponsorship: Conflict of interest in study was not mentioned in of the any application forms. Only single study was sponsored by ICMR. None of study proposal submitted for approval provides information regarding the source of funding involved in conducting the study.

j) Informed consent: Informed consent of the subject was required in 46 studies but only 27 study proposal mentioned about informed consent.

k) Case record form attached: Case record form required to attached in 39 form, however only 8 application forms had attached case record form.

l) Data maintence and storage: None of application forms mentioned about data maintence and storage.

Table 1: Type of studies mentioned in application forms

Type of study	Number
Dissertation	
Observational	62
Procedure related	5
Research studies	
Observational	26
Procedure related	3
Interventional (clinical trial)	4

Table 2: Points mentioned in all application forms

1	Name and signature of principle investigators
2	Name and sign of co- investigators
3	Permission from the head of department & head of institution

Table 3: Factors fail to mention in all application forms

1	Conflict of interest
2	Patient safety factors
3	Compensation given to the participants if risk occur
4	Involvement of vulnerable populations
5	Data maintence and storage of the application forms

Table 4: Discrepancy related to the filling of application form

Discrepancy in	Total (out of 100)	Dissertation (67)	Research(33)
Incomplete title	15	10	05
Permission of interdepartmental	5	4	01
Place of study to carried out not mention in	10	8	02
Study duration not mention in	24	20	04
Informed consent not mention in	19	14	05
Case record form not attached in	61	52	09
Sponsoring authority not mentioned in	99	67	32

DISCUSSION

Ethics review research is essential for projects involving of human subjects to protect the rights and safety of research subjects.[6] It also helps to maintain trust between researchers and society.[7] The purpose of IEC is to ensure quality and consistency in review of clinical research proposals. The IEC follows the ICMR guidelines 2006 and National Ethical Guidelines for Biomedical Research involving human subjects. Guidelines given by ICMR for the requirements of ethics committee, review and decision making process of research .The WHO Guidelines which also helps to Ethics Committees review and approve Biomedical Research proposals involving human participants with a view to safeguard their dignity, rights, safety.[8]

Every IEC have its own written standard operating procedures (SOPs) according to which the Committee should function. The SOPs should be updated periodically based on the changing requirements. In ethics committee the review process consist of procedural issue and proper review of study proposal. The responsibility of an Institutional Ethics Committee (IEC) is to review of all ethical aspects of the project proposals received by it in an Objective manner. IECs members should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

In present study the application forms were according to the standard operating guidelines of ICMR 2006 & WHO Guidelines, however the application form filled by the investigator fail to mention information regarding conflict of interest, patient safety factors, compensation given to the participants if risk occur, involvement of vulnerable populations, maintence of record form.

In the present study highlights the discrepancy in filling of application form such as incomplete title, Permission of interdepartmental, Place of study to carried out not mention in, study duration not mention, informed consent, case record forms, sponsoring authority. These results were similar to study conducted by Sheety et.al.[9] These discrepancies in filling of application forms among the investigators which could due to majority studies were dissertations & the majority of investigators were not skilled in research work during the first year of their admission, improper knowledge regarding the availability of facility & feasibility in-

cluding the procedures or instruments for conduction of study. The review and approval of research synopsis from the ethics committee were occurring in beginning of first year.

It is important duty of both investigators and IEC committee to provide the complete information of study or research, review and analyze in time so that there was no need of repeated meetings for the getting approval of studies. It also helps to increase standards of study.

CONCLUSION

The present study highlights the importance of knowledge and awareness about the filling of the application forms of ethics committee. A uniform well prepared application form of ethics committee required for evaluation and understanding of research project.

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