Original Article

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A Study of Assessing Errors and Completeness of Research Application Forms Submitted to Instituitional Ethics Committee (IEC) of a Tertiary Care Hospital

Pharmacology Section

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ABSTRACT

Introduction: Application form of research work is an essential requirement which is required to be submitted along with the research proposal to the Ethics Committee (EC).

Aim: To check the completeness and to find the errors in application forms submitted to the EC of a tertiary care hospital.

Materials and Methods: The application forms of research projects submitted to the Institutional Review Board (IRB), Government Medical College, Bhavnagar, Gujarat, India from January 2014 to June 2015 were analysed for completeness and errors, with respect to the following - type of study, information about study investigators, sample size, study participants, title of the studies, signatures of all investigators, regulatory approval, recruitment procedure, compensation to study participants, informed consent process, information about sponsor, declaration of conflict of interest, plans for storage and maintenance of data, patient information sheet, informed consent forms and study related documents.

Results: Total 100 application forms were analysed. Among them, 98 were academic and 2 were industrial studies. Majority of academic studies were of basic science type. In 63.26% studies, type of study was not mentioned in title. Age group of subjects was not mentioned in 8.16% application forms. In 34.6% informed consent, benefits of the study were not mentioned. Signature of investigators/co-investigators/Head of the Department was missing in 3.06% cases.

Conclusion: Our study recommends that the efficiency and speed of review will increase if investigator will increase vigilance regarding filling of application forms. Regular meetings will be helpful to solve the problems related to content of application forms. The uniformity in functioning of EC can be achieved if common application form for all ECs is there.

Keywords: Academic, Clinical trial, Industrial

INTRODUCTION

Before any research work or dissertation is carried out, it is very essential to get approval from the Ethics Committee (EC). Application form of research work is an essential requirement which is required to be submitted along with the research proposal to the EC. A completely filled and well designed application form provides the overview of the whole study which helps in the review process of the research work [1-3]. Functions of EC can be described in terms of review of research study, checking properly filled application forms for ensuring privacy, decision making process, confidentiality, safety of the participants and justice issues [2]. But, it mainly depends on the completeness of application form filled by principle investigator.

According to guidelines of World Health Organization (WHO) and Indian Council of Medical Research (ICMR), all necessary documents should be submitted along with application form to EC. EC is responsible for review of all required documents along with submitting application of research project [3].

The process of review may become time consuming and difficult if application forms are incompletely filled. It may also lead to increased workload of EC. Moreover, the requirement is also different for independent and Institutional Ethics Committee (IEC) which leads to difficulties in getting approval for multicentre studies [4-7]. Inadequately filled application forms may create a problem for the EC to understand the essence of proposal and grant the permission.

In view of the above, the present retrospective observational study was carried out to check the completeness and to find the errors in application forms submitted to EC of a tertiary care hospital.

MATERIALS AND METHODS

A retrospective observational study was started after taking approval from Institutional Review Board (IRB) permission. All information collected during study was kept confidential. The application forms of research projects submitted to the IRB, Government Medical College, Bhavnagar, Gujarat, India from January 2014 to June 2015 were analysed for completeness and errors.

The application forms submitted to the IRB were assessed with respect to the following criteria: Type of studies, information about study investigators, sample size, study participants, title of the studies, signatures of all investigators, regulatory approval, recruitment procedure, compensation to study participants, informed consent process, information about sponsor, declaration of conflict of interest and plans for storage and maintenance of data. We also reviewed patient information sheet, informed consent forms and study related documents submitted along with the application form.

STATISTICAL ANALYSIS

Data were expressed in proportion and descriptive statistics were used. All the statistical calculation was done by using Microsoft Excel. Sample size calculations by Master software (version 1.0) indicated that 100 applications would be needed to achieve 80% power with an alpha level of 0.05 (two tailed).

RESULTS

A total of 100 application forms of research projects submitted to the IRB of Government Medical College Bhavnagar from January

2014 to June 2015 were analysed. Among them, we found 98 academic and 2 industrial studies. Majority of academic studies were of basic science type. Among the industry sponsored studies, both studies were phase I trials. The other common types of studies were epidemiological and nutritional products related [Table/Fig-1]. In 63.26% (62) academic studies, type of study was not mentioned in title [Table/Fig-2]. Age group of subjects was not mentioned in methodology in 8.16% (8) academic studies [Table/Fig-3]. In 34.6% (34) academic studies, benefits of informed consent were not mentioned [Table/Fig-4]. Signatures of investigators/ co-investigators/head of department were missing in 3.06% (3) academic studies [Table/Fig-5].

Type of Study	Academic	Industrial
Epidemiological	35 (35.71%)	0
Basic Science	58 (59.18%)	0
Phase I Clinical	0	2 (100%)
Phase II Clinical	0	0
Phase III Clinical	1 (1.02%)	0
Phase IV Clinical	0	0
Clinical Phase Not Mentioned	4 (4.08%)	0

[Table/Fig-1]: Type of studies submitted for the review in the ethics committee.

Disparity in Application Form	Academic	Industrial
Title: use of short forms	4 (4.08%)	0
Type of study not mentioned in title	62 (63.26%)	100%
No information of collaborating industry/ institution	2 (2.04%)	0
Project budget not mentioned	1 (1.02%)	0
Sponsors not mentioned	8 (8.16%)	0

[Table/Fig-2]: Disparity observed in the application forms.

Points in Application Form	Academic	Industrial
Study design stated incorrectly	3 (3.06%)	0
Duration of study not mentioned	1 (1.02%)	0
Study site not mentioned	0	0
Age group of subjects not mentioned	8 (8.16%)	0
Vulnerability not specified	0	0
Mode of recruitment not mentioned	0	0
Any hazardous material/biological sample to be used but not mentioned	2 (2.04%)	0
Frequency of body fluid samples to be collected not mentioned	1 (1.32%)	0

[Table/Fig-3]: Discrepancies in research methodology.

Points in application form	Academic	Industrial
Consent form not prepared	3 (3.06%)	0
Consent not prepared in local language	3 (3.06%)	0
Statement that study involves research not mentioned	4 (4.08%)	0
Purpose and procedures not mentioned	3 (3.06%)	0
Risks and discomforts not mentioned	7 (7.14%)	0
Benefits not mentioned	34 (34.6%)	2 (100%)
Statement that consent is voluntary not mentioned	1 (1.02%)	0
Right to withdraw not specified	1 (1.02%)	0
Confidentiality statement not mentioned	1 (1.02%)	0
Statement related to compensation of participation not mentioned	1 (1.02%)	0
Statement related to compensation of injury not mentioned	1 (1.02%)	0
Amount of compensation not mentioned	21 (21.4%)	100%

[Table/Fig-4]: Errors related to consents of participants.

Points in application form	Academic	Industrial
Missing signatures of investigators/ co-investigators/head of department	3 (3.06%)	0
Permissions from DCGI/HMSC/ institution head not mentioned	0	0

[Table/Fig-5]: Information about regulatory permission
DCGI – Drug Controller General of India, HMSC - Health Ministry Screening Committee

DISCUSSION

Human research has been now increasing in developing countries like India [8]. So, responsibilities of ECs have also been increasing. The review process has many integrated components like checking for completeness of applications form, reviewing consent and other study related documents and scientific and ethical review of research protocol by EC members [9,10]. Incomplete application forms may delays the review process and also increases workload on ECs [11]. According to ICMR guideline, all the elements of application form should be checked and reviewed by EC [3]. A review of literature suggests that there were only few studies conducted in the past which were similar with this study [12]. This paper reviewed common discrepancies which are commonly found in application forms submitted to EC.

Epidemiological and basic science related studies are most commonly found type of studies because these types of studies are common in academic. The most common discrepancies found in academic studies were related to title of studies, information about collaborating centers, type of studies, project budget and compensation related issue. This result is similar with the other study conducted by Shetty YC et al., [2]. It may be because most of the studies are dissertations done by residents so it is possible that they fill application forms improperly. They may not be trained in research methodology or Good Clinical Practice (GCP). The research methodology related training should be included in PG curriculum to improve research quality [13]. An ignorance or increased workload on residents may be other possible reasons. Proper training and awareness may save the time for review process. The funding source and details of budget for any research study should be reviewed by EC according to ICMR guidelines [3]. The information related to budget were not mentioned in 10% of academic studies. It may be because most of the academic studies are self funded so they do not mention about funding of the studies.

The positive findings related to informed consent process were confidentiality statement, statement related to right to withdraw, statement related to compensation of participation and purpose and procedures of the study were included. These results are in accordance with other study conducted by Shetty YC et al., [2]. This shows awareness of researchers about importance of informed consent process in research.

EC can inquire about number of studies conducted by the principle investigator at the same time while he files for the permission for the present/in hand project. Curriculum vitae and GCP training certificate submission is important to ensure adequate qualification and training of investigators undertaking research. It is necessary according to ICMR guidelines [3]. The number of studies cannot be restricted by EC at one time but it can ask investigators regarding their commitment for time. The time allocation can be calculated according to the draft guidelines [14]. The consent form translation is necessary in local language as India is the multi languages country. The back translation should be accurate so that participants can understand undergoing procedures and they can participate into the study. We found adequately in most of the academic studies.

The limitation of our study was that we considered the application forms submitted to a single EC. From our study result we cannot generalize the data as we need to study a larger number of application forms submitted to different ECs of India.

The application form requiring details of investigators and study protocol is desirable because it will be very helpful to EC members to review study methodology. There should be common application form for all the ECs which can be made available online by national regulatory authority [15].

CONCLUSION

Present study found more discrepancies in application forms of academic studies as compared to industrial studies. It can be suggested that regular meetings should be held to solve the problems related to content of application forms. If an investigator is made aware of the issues regarding filling of application forms and the importance of its completeness, than the efficiency and speed of review will increase.

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