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Short Communication

Scientific review committee-an experience from the desk of member-secretary

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ABSTRACT

Writing a proper research proposal is the most important step in conducting a scientific study. Whether the researcher intends to submit the proposal to an ethical committee, research body or funding organization, it is vital that the proposal clearly states why the study is planned, how it is proposed to be conducted and the researcher's commitment to its principles. The current study was carried out to find out common errors committed while submission of research protocol to the scientific review committee (SRC). In 2015, based on feedback and experience of experts in the field and to improve the scientific and technical content of the proposals received, institutional ethical committee for human research was divided into two sub-committees; SRC and institutional ethics committee. This article reports analysis of 100 proposals based on a checklist for submission and discussion during SRC meetings on errors committed. Top ten errors observed were: Incomplete annexure and missing permissions; imprecision and lack of scientific validity in aims and objectives; inappropriate or incomplete statistics; inappropriate; suboptimal instrumentation; lack of clarity on predictor and outcome variables; data collection procedures and analysis lacked completeness; title lacked accuracy and clarity; inappropriate study design; ethical requirements incomplete and sample too small or biased. All errors were reviewed and rectified. Constitution of a separate SRC was found to be effective in providing independent, competent and timely review of all the protocols submitted to it for their scientific merits and feasibility.

Keywords: Institutional ethical committee for human research, Institutional ethics committee, Research protocol, Scientific review committee

INTRODUCTION

A research is usually conducted to fill the gaps in existing knowledge. Although a dissertation is an essential requirement to appear at the postgraduate (PG) exam, it also provides an opportunity to conduct research at tertiary care hospital with a good patient load.[1,2] As a common proverb goes" a good start is half the battle won", writing a proper research proposal is the most important first step in conducting a scientific study. A research proposal is a promise made by the researcher to the organization in particular and society at large. It should convey the various components in such a manner that anyone reading the proposal will be able to replicate the study if desired. Whether the researcher intends to submit the proposal to an ethical committee, a research body or funding organization, it is vital that the proposal clearly states why the study is planned, how it is proposed to be conducted and the researcher's commitment to its principles. In other words, "anatomy of research is the set of tangible elements that make up the study plan and the physiology of research is how the study works".

The current study was carried out to find out common errors committed while submission of research protocol to the scientific review committee (SRC). And later to

conduct research methodology workshop for PGs to incorporate topics where most errors were noted.

METHODS

Institutional ethical committee for human research (IECHR) at the medical college studied was functioning as a single committee for several years. In 2015 based on feedback and experience of experts in the field, for better coordination and monitoring and to improve the scientific and technical content /appropriateness of the protocols received it was divided into two sub-committees; scientific review committee (SRC) and institutional ethics committee (IEC) as shown in Figure 1.

SRC has been constituted under the authority of the Dean Medical College. The SRC is multidisciplinary in composition and includes individuals with relevant scientific expertise, balanced age and gender distribution. SRC is independent from political, institutional, professional and market influences. It has due regard for the requirements of relevant regulatory agencies and applicable laws. The functions and duties decided were to; provide independent, competent and timely review as well as approval to all the protocols submitted, for their scientific merits and feasibility and; conduct research methodology workshops for students and faculties. Once the protocols were reviewed by SRC, they were then scrutinized by the IEC. The author reports an experience while working as member-secretary of this newly formed SRC.

Figure 1: Structure of institutional ethical committee for human research (IECHR).

RESULTS

Fourteen (14) SRC meetings were conducted in 2016. A total of 145 proposals were reviewed, of which 14 were resubmitted and re-reviewed during 2016. This article reports analysis of 100 randomly selected proposals based on a checklist for submission and discussions during SRC meetings on errors committed as shown in Table 1. Additionally, 20 dissertations submitted to the university for evaluation and being accepted during 2012 to 2015 were randomly selected from all disciplines, not for comparison but to incorporate domains to be included in PG workshops for appraisal.

Table 1: Analysis of reviewed protocols and submitted dissertations.

Analysis	Submitted dissertations (N=20)	Protocols reviewed (N=100)	
Anatomy of research	**Errors noted in**	**Errors noted in**	**Type of errors committed**
Title of the study			
Appropriate and clear (Title should include independent variable, dependent variable, study population and settings/ area of study. Title should be evaluated at the end)	6 (30%), not appropriate	38, not appropriate	Short forms mentioned, e.g., "proximal humerus fractures treated with PHILOS plating"; not aligned with objectives; grammatical mistakes like that of is, a, an, the
Introduction			
Brief introduction; purpose/need of the study/lacunae in present knowledge hence there is need to do the study; uniqueness of the study	8 (40%)	11	Need for the study missing; grammatical errors; written in past tense; formatting errors (font size and paragraph mainly); cut, copied, pasted from literature without reading; material not a part of bibliography or reference list
Aims and objectives			
Aims only if required, precise and scientifically sound	12 (60%)	73	Difference between aims and objectives not clear; recommendation before conduction of study was part of objectives in a few; grammatical errors; action verb

Continued.

Analysis	Submitted dissertations (N=20)	Protocols reviewed (N=100)	
			missing; objectives which were not to be measured added
Methodology			
Study setting, study population	0	0	Mentioned in all
Study duration	0	27	Not mentioned
Study design	11 (55%)	35, not appropriate	Lack of concept of primary and secondary data; lack of concept of follow-up study/longitudinal and cohort study; blinding, confounders, matching not clearly stated where necessary; follow-up not mentioned when required
Sampling and sample size	6 (30%)	32	Pilot study or base line study to calculate sample size not mentioned; base line study not added in the reference list; proposal submitted very late, sometimes during starting of third year, so sample size was compromised in many; if time bound study or convenient sample, the same was not mentioned
Inclusion/exclusion criteria	0	31	Lack of uniformity in terms of investigations; copied and pasted from other studies directly with their superscripted references; operational definition e.g. morbid patients/diseases not given
Interventions and its method (where appropriate)	1 (5%) There was one dissertation on interventional study and that was community trial. The same was misunderstood	10/30 There were 30 intervention al study proposals	Details of surgery, equipment or procedures either not given or incomplete; proper reference to /source missing mainly for equipment/tools, classifications, scorings
Predictor and outcome variables	0	44	Lack of clarity, outcome not mentioned and if done then not aligned with objectives/analysis
Data collection procedures and data analysis	3 (15%)	41	**Study tool:** type of question (closed, open) not clear**;** choosing right technique (interview wrongly interpreted as self-administered questionnaire)**;** extra information collected, formatting errors**;** methods in proforma not aligned with objectives **Analysis:** Missing codes, scores, headings, follow-up table, title; lack of concept of qualitative and quantitative variables software not mentioned
Statistical methods to be used	1 (5%)	50	**Statistical tests** either not mentioned or not justified/not appropriate; lack of concept of Likert scale (for scales/scores); lack of understanding of random sampling and randomization; not aligned with objectives or outcomes; in few not mentioned at all; lack of concept of use of association and correlations (mainly in histopathology, radiology and clinical departments)

Analysis	Submitted dissertations (N=20)	Protocols reviewed (N=100)	
Ethical issues; informed consent process (ICP), patient information sheet (PIS); confidentiality issues and data safety	11 (55%)	30	ICP and PIS missing; not translated in vernacular language; risk not mentioned correctly; assent forms not attached; title/dept/hospital name missing
Relevant references (reference list - accurate and complete preferably of last 5 years), one full similar study	1 (5%)	53	Common errors: old (>10 years), lacked concept of styles, lack of accuracy and completeness; lacked concept of reference and bibliography; sources in the protocol missing from references /annexure
Annexure	-	100	Forwarding letter/assurance letter: not signed by student/HOD/not addressed properly/date missing/no clarity on type of submission. Application: year of admission missing/funding source not mentioned in funded studies. Permissions: lab details if sent outside, essential permissions from superintendent, dean, head of depts. of other applicable departments missing. Medical officer of health (MOH), chief district health officer (CDHO), funding agency permissions were missing
Physiology of research			
Results	3 (15%) Results: Tables and graphs titles in-complete and not aligned with objectives and statistics Confounding factors not studied or written, affecting validity		-
Discussions	11 (55%) Problem in writing discussion in line with the review of literature, recommendations being vague and not precise or not aligned with the results		-

Continued.

They were evaluated using a Likert scale for overall impression as follows: poor: 1-5; good: 6-8; very good: 9-10. The distribution of these 20 dissertations was; three from medicine, two each from general surgery and pathology and one each from paediatrics, psychiatry, orthopaedics, ophthalmology, obstetrics gynaecology, anaesthesia, radiology, anatomy, physiology, biochemistry, pharmacology, microbiology and preventive and social medicine. The overall impression was; seven of them were scored as poor, nine as good and only four could make it up to very good. In those four the strengths were; the tables, references style and completeness, research idea being novel, review of literature being recent and relevant and in one a good attempt was made to use both qualitative and quantitative methods. In rest of them the errors committed are shown in the Table 1. The type of errors was almost similar in the protocols submitted and accepted dissertations.

As shown in table, top ten errors were observed to be; annexure incomplete and missing permissions; aims and objectives lacked precision and scientific soundness; references were old, inaccurate and incomplete; inappropriate or incomplete statistics; inappropriate or suboptimal instrumentation; lack of clarity on predictor and outcome variables; data collection procedures and data analysis lacked completeness; title lacked accuracy and

clarity; inappropriate study design; and incomplete ethical requirements, sample too small or biased. All errors were rectified by the students after obtaining feedback and finalized by the member-secretary.

To add, two research methodology workshops for PGs and their guides were conducted under SRC during 2017. All topics where most errors were noted were incorporated and the study findings were appraised. This was followed by a brief oral feedback session from few participants and anonymous written feedback from all. There was a suggestion to undertake such a workshop within three months of joining the PG course.

DISCUSSION

In two studies reviewed, the top ten reasons for rejection were: inappropriate or incomplete statistics; over interpretation of results; inappropriate or suboptimal instrumentation; sample too small or biased; text difficult to follow; insufficient problem statement; inaccurate or inconsistent data reported; incomplete, inaccurate, or outdated review of literature; insufficient data presented; and defective tables or figures. The main strengths noted in accepted manuscripts were the importance or timeliness of problem studied, excellence of writing, and soundness of study design.[3,4] These reasons are similar to errors committed while submission of protocol to SRC in the current article.

CONCLUSION

"Research graced with ethics, evidence and elegance" is a great achievement. However, such evidence from dissertations and faculty-initiated research projects can find place in good journals only when the proposal is sound with adequacy of the study design and it has been conducted meticulously as planned. Constitution of a separate SRC was found to be effective in providing independent, competent and timely review of all the protocols submitted to it for their scientific merits and feasibility. It also identified domains to be included in research methodology workshop. Such separate committee in each medical college is recommended.

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