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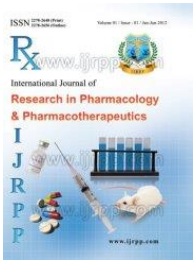

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Comparative analysis of distribution patterns of research protocol: a retrospective, observational study

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ABSTRACT

BACKGROUND

Before starting any research study, a review and approval by Institutional Ethics Committee and Institutional Review Board has become mandatory. The ultimate goal of research is to safeguard the public health or population and thus every human has the right to understand the nature besides the risks and benefits of research. Only after approval, a study can be carried out keeping in view any modifications required to meet the regulatory requirements. Both thesis and independent research projects need permission of the IEC & the IRB to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The committee also examines compliance with all regulatory requirements, applicable guidelines and laws.

OBJECTIVE

To have an insight into the research pattern for 2 years in a tertiary care teaching hospital this study was undertaken.

MATERIALS & METHODS

The present retrospective, observational study was conducted in the Deptt. of Pharmacology, Govt. Medical College, Jammu after taking permission from Institutional Ethics Committee. IEC record of year 2014 and 2015 was assessed and compared. Different patterns of various research proposals both thesis and independent research proposals was assessed. A tertiary care hospital of north india, IEC GMC jmu is registered with the DCGI. An attempt was made to strictly follow the confidentiality while making analysis.

RESULTS

A total of 244 research projects were submitted and got approval from IEC. 116 research projects were submitted in 2014 out of which 85 (73.2%) were thesis projects and 31 (26.7%) were independent research projects. 128 research projects were submitted in 2015 out of which 88 (68.7%) were thesis research projects and 40 (31.2%) were independent research projects. Most thesis proposals fell in category B or B/C whereas most independent proposals fell in category B/C or C.

CONCLUSION

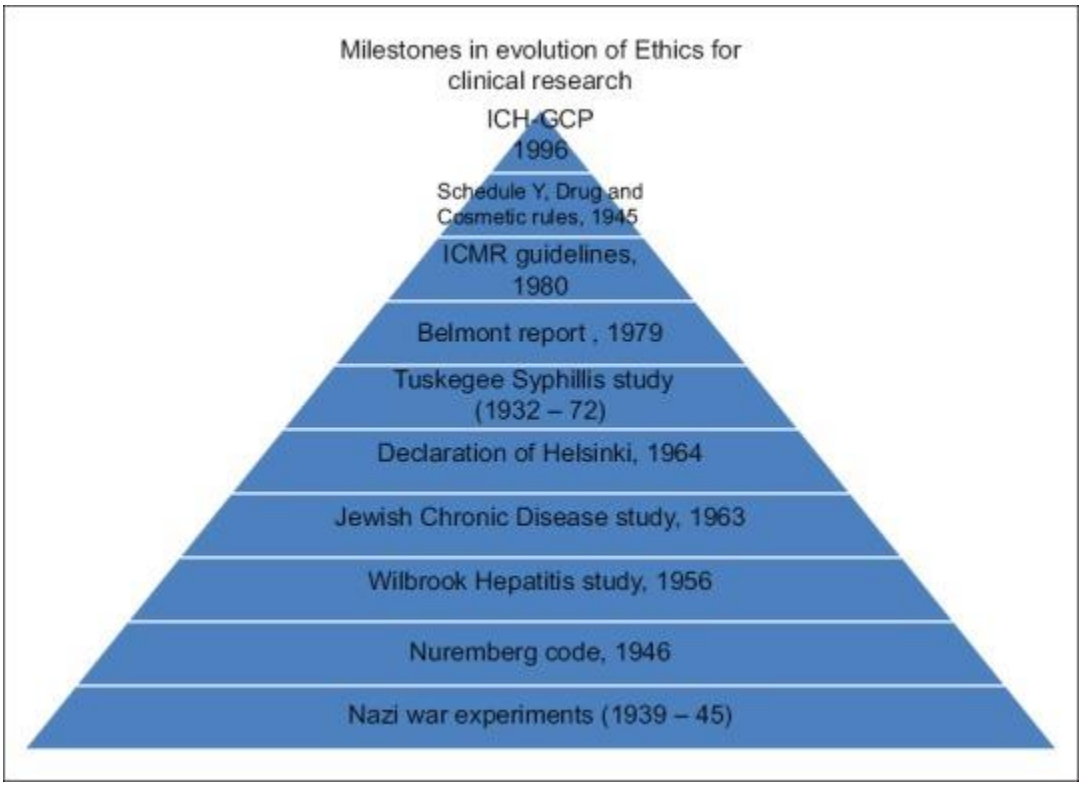
A similar trend was followed in both the years but a rising trend was seen among the independent research projects. It may be because of the new accredition policy and research rider by Medical Council of India

Keywords: Institutional Ethics Committee, Institutional Review Board, Research

INTRODUCTION

Ethics are the moral values of human behavior and the principles which govern these values. Every profession is bound by code of ethics and the essence of medicine as a moral community dates back to Hippocratic Oath. This oath was a guide for the physician on professional ethics to place the interests of their patients above their own interests. [1] The situation becomes challenging for a doctor when he/she assumes the role of researcher. The doctor-researcher has to serve both the roles, the zeal of an investigator that has the potential to cloud the morality of the physician inside. Thus, it was realized that code of ethics for clinical research were needed and guidelines for human research were framed.

This need was reflected from the time of World War II, when 23 Nazi doctors were convicted for conducting trials on concentration camp inmates, the judgement termed as Nuremberg Code. [2] Over a period of time, World Medical Association (WMA) General Assembly (Helsinki, Finland, 1964) developed a set of good clinical practice guidelines to safeguard the rights and well-being of subjects participating in clinical research. This was referred to as the *Declaration of Helsinki*. [3] Various countries drafted their own guidelines of GCP, and in India, the Indian Council of Medical Research (ICMR) first released a policy statement on ethical considerations involved in research on human subjects in 1980. In India, the ethics guidelines are given the legal status by way of Schedule Y Drugs and Cosmetics Rules, 1945.[4] With the advent of multicentric studies involving different countries, having a uniform GCP was a felt-need. For this purpose, the International Conference on Harmonisation-GCP was developed in 1996. [5]



Biomedical research involving human participants requires mandatory approval from an appropriately constituted institutional ethics committee (IEC), also referred to as the institutional review board (IRB), ethics review board (ERB) and research ethics board (REB) in other countries. Ethics committee is an independent body that plays the pivotal role in ensuring that a trial is conducted in accordance with GCP guidelines and to safeguard the safety and well-being of subjects participating in a clinical trial, after making them understand the risks & benefits of the same. It ensures a competent review of all the ethical aspects of the project proposals submitted its complance to all regulatory

requirements and does it free from any bias or external influence. [6]

Government Medical College Jammu, being a tertiary level teaching institute, research proposals are submitted both by the faculty, post graduate students consisting of thesis and independent research projects before the Institutional Ethics Committee. It comprises of a minimum of five persons required to form the quorum without which a decision regarding the research would not be taken. The quorum would have at least one representative from the following group: 1. One basic medical scientist (preferably one Pharmacologist) 2. One Clinician 3. One legal expert or retired Judge 4. One social scientist/ representative of non-governmental organization/ Philosopher/ Ethicist/ Theologian or a similar person 5. One lay person from the community. [7]

Only after thorough deliberation by the committee on the objectives, design, rationale, computations, risks & effects on the participant population, benefits of the outcomes of the study, compensations the study can be carried out keeping in view any modifications required to meet the regulator y requirements. [8]

There is a lot of literature about the constitution, responsibilities & working of the IEC/IRB but we were unable to cite any study where the distribution of patterns of the research being presented to the committee were done in any institute. In this context, this study was undertaken, to have an insight into the research pattern of the proposals submitted before the IEC of GMC Jammu over the span of 2 years in this tertiary care teaching hospital.

The aim of this study was to investigate trends in research protocols of IEC of Govt. Medical College Jammu. The outcome of this study will be useful for the IEC/IRB to form revised policies & regulations with regard to approval of research proposals in any institute.

MATERIALS & METHODS

The present retrospective, observational study was conducted in the Deptt. of Pharmacology, Govt. Medical College, Jammu after taking permission from Institutional Ethics Committee. A tertiary care hospital of north india, IEC GMC jmu is registered with the DCGI.

IEC records of the years 2014 and 2015 was assessed thoroughly and compared with each other. The total number of thesis & independent research proposals submitted were calculated & the speciality to which each study belonged was computed and tabulated for both the years. Different patterns of various research proposals both thesis and independent research proposals were assessed.

For the purpose of smooth deliberation on the proposals and convenience of thorough assessment, the research protocols according to the Standard Operating Procedures of the Indian Council of Medical Research were divided to Categories A, B, C. Category A studies included New Drug trials/studies, Surgical or diagnostic procedure trials being carried for the first time in the institution, New drug trials on high risk population. These were subjected to a full review by the committee. Category B included drug trials for a different indication/ intervention trials other than the routine protocols being conducted in the institute. These are subjected to an expedited review by the committee. Category C included observational studies, where the patterns or analysis was collected from patients under the already undergoing treatment plans. These are subjected to an exempted review. [9] A category B/C was created at IEC, GMC, Jammu for ease & convenience of assessment that included the studies with routinely done interventions/treatment plans. All the proposals that were modified or sent for changes by the committee over both years, were computed. An attempt was made to strictly follow the confidentiality while making this analysis.

The number of entities in each category was analysed for both the years, while inter group comparison between two groups was done by unpaired t-test. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 244 research projects were submitted and got approval from IEC/IRB. 116 research projects were submitted in 2014 out of which 85 (73.2%) were thesis projects and 31 (26.7%) were independent research projects. 128 research projects were submitted in 2015 out of which 88 (68.7%) were thesis research projects and 40 (31.2%) were independent research projects. On comparison, there was no statistically significant difference between the two groups. **(Table 1)**

Table 1: Showing research projects in 2014 & 2015

CATEGORIES OF RESEARCH PROJECTS	2014(%)	2015(%)	P VALUE (CHI SQUARE TEST)
THESIS	**85 (73%)**	**87 (68.5%)**	**P=0.4805(not significant)**
INDEPENDENT RESEARCH PROJECTS	**31 (26.72%)**	**40 (31.4%)**	**P=0.4805(not significant)**

On comparing the proposals from both the years, the highest number of independent research proposals were from the surgical department (28.3% & 27.7%) followed by the biochemistry department (13.4% & 20.8%). **(Table 2)**

Table 2: Showing Speciality of Various Independent Research Projects

Intervention	2014(%)	2015(%)
Medicinal/ Drug Safety	**6 (8.9%)**	**5 (6.9%)**
Radiological	**3 (4.5%)**	**6 (8.3%)**
Surgery	**19 (28.3%)**	**20 (27.7%)**
Histopathological	**6 (8.9%)**	**2 (2.7%)**
Biochemistry	**9 (13.4%)**	**15 (20.8%)**
Others	**24 (35.8%)**	**24 (33.3%)**

On the other hand, the highest number of thesis projects were submitted from the deptt. of general medicine (14.11% & 11.4%), surgery (11.5%& 13.7%) and gynae/obs(10.5% & 10.3%) whereas least number was submitted by deptt. of dermatology and blood transfusion in both the years(2.3% & 2.2%). **(Table 3)**

Table 3: Showing Speciality of Various Thesis Projects

Speciality	2014(%)	2015(%)
Anesthesia	**4(4.7%)**	**4(4.5%)**
Ophthalmology	**4(4.7%)**	**5(5.7%)**
Surgery	**10(11.5%)**	**12(13.7%)**
Pharmacology	**5(5.8%)**	**5(5.7%)**
Gynae/Obs	**9(10.5%)**	**9(10.3%)**
Medicine	**12(14.11%)**	**10(11.4%)**
Orthopaedics	**6(7%)**	**4(4.5%)**
Pathology	**8(9.4%)**	**5(5.7%)**
Dermatology	**2(2.3%)**	**2(2.2%)**
Anatomy	**4(4.7%)**	**5(5.7%**

ENT	**6(7%)**	**6(6.8%)**
Radiology	**3(3.5%)**	**3(3.4%)**
PSM	**3(3.5%)**	**5(5.7%)**
Physiology	**4(4.7$)**	**4(4.5%)**
Paedriatics	**3(3.5%)**	**3(3.4%)**
Blood transfusion medicine	**2(2.3%)**	**2(2.2%)**

These projects were categorized into different categories and no project was submitted belonging to cat. A in both the sessions. In 2014, 20 thesis projects (23.5%) were falling in cat. B, 49 projects (57.6%) in cat. B/C and 16 projects (18.8%) in cat. C. In 2015, 25 thesis projects were falling (28.4%) were falling in cat. B, 46 projects (52.27%) in cat. B/C and 17(19.3%) in cat. C.

Whereas, about independent research projects, 5 (16.12%) were falling in cat. B, 3(9.6%) in cat. B/C and 24(77.4%) in cat. C in the year 2014 and 7 (17.5%) in cat. B, 19 (47.5%) in cat. B/C and 14 (35%) in cat. C in 2015. Number of independent protocols in 2015 was significantly higher. **(Table 4)**

Table 4: Showing Categories of Research in 2014 & 2015

CATEGORY	**THESIS**		**P VALUE (CHI SQUARE TEST)**	**INDEPENDENT RESEARCH PROJECTS**		**P VALUE (CHI SQUARE TEST)**
	2014(%)	**2015(%)**		**2014(%)**	**2015(%)**	
A	**0**	**0**		**0**	**0**	
B	**20 (23.5%)**	**25 (28.4%)**	**P= 0.489 (not significant)**	**5 (16.12%)**	**7 (17.5%)**	**P=1 (not significant)**
B/C	**49 (57.6%)**	**45 (52.3%)**	**P=0.448 (not significant)**	**3 (9.6%)**	**19 (47.5%)**	**P=0.0006 **(significant)**
C	**16 (18.8%)**	**17 (19.3%)**	**P=1 (not significant)**	**24 (77.4%)**	**14 (35%)**	**P=0.0009 **(significant)**

Most of the thesis & independent research protocols were approved without any modifications; others after modifications were approved for ahead. None of the proposal was rejected for both the years in both categories. **(Table 5a&b)**

Table 5a: Showing Modifications Done In Thesis Protocol in 2014 & 2015

	2014	**2015**	**P VALUE (CHI SQUARE TEST)**
APPROVED WITH MODIFICATIONS	**CAT B-2,CATB/C-13,CAT C-1 TOTAL-16 (18.8%)**	**CAT B-19, B/C-2 , C-2 TOTAL -23 (26.5%)**	**P=0.276 (not significant)**
APPROVED WITHOUT MODIFICATIONS	**69(81.1%)**	**64(73.5%)**	**P=0.276 (not significant)**
NOT APPROVED	**0**	**0**	

Table 5b: Showing Modifications Done In Independent Research Protocol in 2014 & 2015

	2014	2015	P VALUE (CHI SQUARE TEST)
APPROVED WITH MODIFICATIONS	**4 (12.9%)**	**3 (7.5%)**	**P=0.691 (not significant)**
APPROVED WITHOUT MODIFICATIONS	**27 (87.09%)**	**37 (92.5%)**	**P=0.691 (not significant)**
NOT APPROVED	**0**	**0**	

DISCUSSION

Under schedule Y of the Drugs and Cosmetics Rules 1945, amended in 2005, in India, any agency conducting biomedical research using human subjects requires the approval of its research protocol from an ethics committee before the commencement of a clinical trial/research study. [10] Schedule Y also elaborately sets forth the structure and function of the IEC, and gives a detailed explanation of the approval letter. Further, it prescribes that the ICMR guidelines be followed, thus indirectly giving these guidelines the status of a law. [11] The Drug Controller General of India (DCGI), under the Central Drugs Standard Control Organisation (CDSCO), made registration mandatory for these Ethical Committees which approve clinical trials. [12]

The proposals assessed under our study were divided to thesis or independent research protocols, thesis protocols being far greater in number in both the years.This was due to the mandatory requirement for ethical clearance of thesis protocols for all postgraduate students. Moreover, in this context, Levine et al in their study state that all members of the IEC/IRB must endeavor to share the researcher's burden in seeking a balance between the pursuits of scientific interests on the one hand and the needs of society and the rights of research subjects on the other**. [13]**

The proposals were divided into categories depending on the nature of the study, to observational and interventional studies. Observational studies, classified under category C are mostly those evaluating serum samples, histopathology specimens, parameters or simple questionnaires in normal subjects/patients Interventional may include procedures or drug trials classified under category C. Thatte et al, gave a similar classification of research in their review study**. [14]**

The number of independent research proposals was statistically higher in subsequent year, which maybe due to the accredition policy and research rider by the Medical Council of India that requires mandatory publications by the applicant. Registration of clinical trials in some type of public registry has become a requirement for publication by the International Committee of Medical Journal Editors**.[15]** Although the increase in registered clinical trials over time is due to new registration requirements, there has undoubtedly been an increase in the number of trials conducted worldwide.

Most of the proposals in our study were accepted without modification, only some were accepted with the required regulatory modifications. These findings are mirrored in the audit study by Wise et al. [16]

CONCLUSION

IEC is the backbone of ethical research in our institute. Most of the trends of thesis proposals were similar during both the years, but as far as independent research peojects were concerned, they increased significantly in the subsequent year, which may be due to the research rider & accredition policy by the MCI.

This being a single centre study covering two years of working of IEC, more extensive research needs to be done to study the functioning & responsibilities of the IEC to depth at a multicentre level, form new regulations and policies for the benefit of the researcher as well as the participants.

Conflict of Interest: Nil

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