

Mukta Sunil Kuyare,
Parag Vijayrao Sarve¹,
Komal S. Dalal¹,
Raakhi K. Tripathi²

Departments of Central Sterile Supply
and ¹Medical Research, Bhaktivedanta
Hospital and Research Institute, Thane,
²Department of Pharmacology,
Seth G S Medical College and KEM
Hospital, Mumbai, Maharashtra, India

Address for correspondence:

Dr. Parag Vijayrao Sarve,
Department of Medical Research,
Bhaktivedanta Hospital and Research
Institute Srishti Complex, Mira Road,
Thane - 401 107, Maharashtra, India.
E-mail: dr.paragsarve@gmail.com

Abstract

Evaluation of performance of the Medical Research Department in 'Research naive' non-academic hospital: An audit

Introduction: Conducting medical research is not limited to academia and pharmaceutical industry but even multispeciality hospitals need to venture in this area along with patient care. To develop research culture among well-established non-academic hospital is always difficult and challenging task. This article attempts to evaluate the performance of the department in 'Research naïve' hospital in the last two years and review the strengths and challenges it faced at each step. **Methods:** This was a retrospective document analysis study evaluating the steps towards setting and sustaining of Medical Research Department of Bhaktivedanta Hospital during the period of January 2013 to June 2015 (30 Months). The authors developed a checklist (along with performance indicators) to assess the Preparatory phase and Activity phase of the research department which were evaluated by Institute Quality Management Team. Each step of both phases was also reviewed in terms of strengths and challenges as perceived by the authors. **Results:** During 2 year journey of research naïve Hospital, Institute had witnessed Hospital initiated (n=24, 59%) and sponsored projects (n=17, 41%) in all specialties. HRC reviewed (n=2.13) projects per meeting for administrative consideration while IEC reviewed (n=2.15) projects for scientific and ethical review. Challenges during preparatory phases were circumvented by immense cooperation of hospital management for initial investment, sensitization through research workshops for consultants, established procedures and trained support manpower and constant encouragement by research coordinator. **Conclusion:** Considering evaluation of 41 studies in very first 2 years in 'Research naive non academic institute demonstrated successful implementation of trio model of Hospital Research Committee for administrative review, IEC for scientific-ethical review, centralized MRD for coordinating all research projects under one roof which may act as role model for Research naive institutes

Key words: Institutional Ethics Committee challenges, Medical Research Department, Research Institute, solutions

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Quick Response Code:



Website:

www.picronline.org

DOI:

10.4103/2229-3485.192041

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How to cite this article: Kuyare MS, Sarve PV, Dalal KS, Tripathi RK. Evaluation of performance of the Medical Research Department in 'Research naive' non-academic hospital: An audit. *Perspect Clin Res* 2016;7:174-80.

INTRODUCTION

Medical research is an integral part of health care as it attempts to find out newer medicines on existing diseases and combat changing diseases scenarios. It is time-tested among all stakeholders of healthcare industry that medical research is mutual beneficence model to patients, doctors, and ultimately to society. Medical research is not limited to academia and pharmaceutical industry, but even multispecialty hospitals need to venture in this area along with patient care.

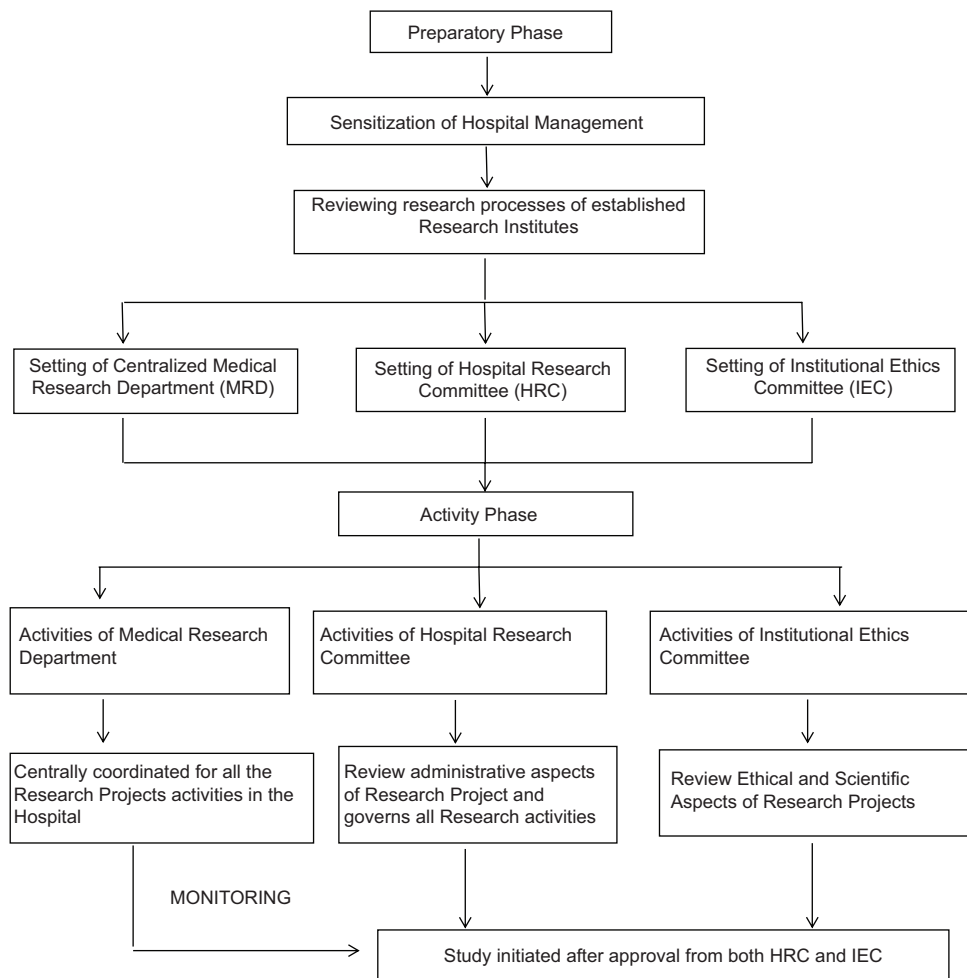
The BhaktiVedanta hospital is multispecialty tertiary 200 bedded hospital established in 1998 and continues to provide modern scientific, spiritual, and holistic health care. In due course, hospital management realized after establishing name in healthcare; they should head toward medical research, but there was no inclination of hospital consultants toward research culture even after 15 years from its inception. The hospital administration set up the Medical Research Department (MRD) in March 2013. This article attempts to evaluate the performance of the MRD

in “Research naïve” hospital in the last 2 years and review the strengths and challenges faced at each step.

Study methodology

This was a retrospective (January 2013 to June 2015, i.e., 30 months) document analysis study. Permissions from the Institutional Head and Institutional Ethics Committee (IEC) were taken prior to the conduct of the study. Privacy and confidentiality were strictly maintained. While reviewing the documents, the authors for convenience divided the processes under two phases-preparatory phase and activity phase [Flowchart 1].

The preparatory phase included all the processes from thought to action of setting of the MRD, Hospital Research Committee (HRC), and the IEC. The hospital management was sensitized and arranged workshops on research methodology for their in-house consultants. Subsequently, the hospital management approached renowned institutions for guidance including private and government medical institutes to learn the basic requirements of the MRD set up and the working of



Flowchart 1: Setting of research culture in research naive hospital

IEC. Hospital appointed staff experienced in research methodology to initiate this endeavor. The need to establish administrative governing body with mixed experiences in administration and research was identified, and MRD was set up. The MRD formed the HRC under the chairmanship of Hospital director along with 5 other members of the institute to provide guidance, scientific review, and technical support to research projects. For conduct of any biomedical research, it must be approved

by an IEC which is set in accordance with Schedule Y and ICMR guidelines (2006).^[1] Thus, the hospital management further also formed an IEC constituting of both internal and external members'. The IEC – Standard operating procedures (SOPs) were prepared, approved, and all IEC members received training in ICH-GCP, Ethical review process and IEC-SOPs. The hospital went further to register the IEC with DCGI office and received registration in June 2013. Post IEC registration, the HRC, and IEC

Table 1: Performance indicator for preparatory and activity phase

Phase	Indicator
(A) Preparatory phase (January 2013 to June 2013)	
(a) Sensitization of Hospital Management	(i) Number of sensitization workshop on research (ii) Number of consultants attended the workshop (iii) Number of consultants inclined to do research postworkshop
(b) Reviewing research processes of established Research Institutes	(i) Number of institute approached to study process of setting Research Department
(c) Setting of centralized Medical Research Department	(i) Number of full-time staff appointed, designation, and qualification
(d) Setting of HRC	(i) Type of selection criteria developed to be member (ii) Number of staff approached to be committee members (iii) Number of staff agreed to be committee member (iv) Number of SOPs prepared for various activities, type of activity (v) Duration to prepare SOPs
(e) Setting of IEC	(i) Number of persons (external/internal) approached to be IEC members (ii) Number of persons agreed to be IEC member (iii) Number of SOPs prepared for various activities, type of activity (iv) Duration to prepare SOP (v) Number of introductory training workshop for ethical review and SOP training (vi) Time taken to register the IEC with CDSCO
(B) Activity phase (July 2013 to June 2015)	
(a) Activities of Medical Research Department	(i) Number of research training workshops conducted (ii) Total number of research projects (iii) Total number of investigator initiated research projects (iv) Total number of sponsored research projects (v) Number of consultant/study staff involved per research projects (vi) Total number of patient recruited during July 2013 to June 2015 (vii) Average number of patient recruited per study (viii) Percentage of patient drop out/lost to follow-up (ix) Total number of protocol deviation reported to ethics committee (x) Number of manuscripts received for publication
(b) Activities of HRC	(i) Total number of research committee meeting and average per month (ii) Average number of research committee members attended per meeting (iii) Total number of study projects submitted or reviewed/meeting (iv) Total number of study projects approved/meeting (v) Number of study projects submitted per month (vi) Total number of queries raised per projects (vii) Average research committee approval time per projects (from date of submission to date of approval) (viii) Total number of SAE reviewed by Head of institute (chairperson of HRC)
(c) Activities of IEC	(i) Total number of ethics committee meeting (ii) Average number of ethics committee members attended per meeting (iii) Total number of study projects reviewed/meeting (iv) Total number of study projects approved/meeting (v) Number of study projects submitted per month (vi) Total number of queries raised per projects (vii) Number of scientific queries raised per projects (viii) Number of ethical queries raised per projects (ix) Number of administrative queries raised per projects (x) Average ethics committee approval time per projects (from date of submission to date of approval) (xi) Total number of SAE submitted and reviewed by ethics committee

IEC=Institutional Ethics Committee, SOPs=Standard operating procedures, SAE=Serious adverse event, HRC=Hospital research committee

started functioning by review research proposal which was considered as the activity phase by the authors.

The authors developed checklist for preparatory phase and activity phase [Table 1] which was reviewed by two members of the Quality Management Committee of Institute. Preparatory phase was reviewed for each steps including sensitization of hospital management, establishing of research process, setting of MRD, setting of IEC, and setting of (HRC). The HRC and HEC activities were reviewed against submission of research proposal for review. Each step of both phases was also reviewed regarding strengths and challenges.

RESULTS

Performance indicators along with strengths and challenges were as follows:

Preparatory phase

Sensitization of hospital management and consultants

The hospital management arranged workshops ($n = 2$) on research methodology, ICH-GCP, and scientific writing which was attended by 45/120 and 72/120 consultants, respectively. Post workshop feedback revealed that 36 consultants were motivated to conduct research studies.

Strengths

- Proactive hospital management
- Initial financial investments to kick start MRD activities.

Challenges

- Difficult to convince the hospital trustees considering the nonfinancial benefits of research
- Apathy of the consultants of the hospital to adopt research culture, citing their busy schedule, and complex documentation
- Very few consultants ($n = 11$) were experienced, but none in multidisciplinary research.

Reviewing processes of established research institutes

The hospital management approached the renowned institutions ($n = 2$). One government and Private Medical Institute for guidance on setting MRD and sent ($n = 3$) hospital staffs including consultant, microbiologist, and the principal of the nursing school for training.

Strengths

- Motivated and trained members ($n = 3$) in national and international ethical guidelines and ethical review of

clinical studies were sent to review research process of other institute

- Institutes approached were cooperative and provided adequate guidance.

Challenges

- Convincing the consultants the need to set up MRD.

Setting of centralized Medical Research Department

One of hospital acupuncture consultant trained in clinical research and bioethics served as “Advisor” and a full-time Medical “Research Coordinator” with Masters in Clinical Research and experienced in research setting research ($n = 2$) were appointed to initiate this endeavor.

Strengths

- Trained, experienced MRD staff
- Hospital administration provided space for MRD.

Challenges

- The manpower was limited ($n = 2$) to set up and govern all medical research-related activities of MRD
- The MRD while conducting clinical trials with new drugs had to comply with regulations governing clinical trials and required registration of the Ethics Committee and accountability from the head of the institute.^[2]

Setting of Hospital Research Committee

Internal members with at least 2 years of experience in Research Administration were accepted as selection criteria. Totally, $n = 6$ members were agreed to be part of HRC after approaching $n = 8$ members. The MRD-SOPs were prepared, reviewed, and approved in a span of 4 weeks. At present, there were $n = 8$ SOPs on HRC activities, procedures prior to study initiation, and during the study including informed consent procedures, documentation, safety reporting, investigational product storage, study closeout, and procedures for investigator-initiated studies.

Strengths

- Motivated and dedicated members formed the HRC
- SOPs were in compliance with regulatory and ethical requirements.

Challenges

- Create awareness in the hospital about MRD and HRC activities
- To train hospital staff on SOPs and monitoring of compliance of SOPs in research studies.

Setting of Institutional Ethics Committee

For selection of external members, there were an additional selection criteria of experience of at least 2 years in

clinical research and ethical review. During selection of IEC members, total 19 persons including scientific ($n = 10$, external $n = 4$, internal $n = 6$) and nonscientific members ($n = 9$, external $n = 7$, internal = 2) were approached to be IEC member; however, only 13 persons including scientific ($n = 7$, external $n = 3$, internal $n = 4$) and nonscientific members ($n = 6$, external $n = 5$, internal = 1) agreed to be IEC member. IEC SOPs, which included $n = 14$ sections including membership details, review process, record retention, review of serious adverse events (SAE) reports, review of proposals involving vulnerable population, etc., were prepared, reviewed, and approved within 5 weeks. All IEC members received frequent intermittent training ($n = 3$) on ICH-GCP, ethical review process, and IEC-SOPs. The IEC received CDSCO registration in June 2013 without any query within $n = 49$ days from application submission.

Strength

- Experienced external IEC members and administrative staff served as asset.

Challenges

- Apprehension and reluctance of consultants to join the IEC as internal scientific members
- Being a private nonteaching hospital selection of quorum members of IEC, i.e., basic medical scientist, layperson, and legal expert was difficult. In addition, lawyer/lay person had to be trained and briefed as to what is expected out of them while serving on an IEC
- The secretary of IEC had to be trained in the administrative aspects of EC.

Activity phase

Activities of Medical Research Department

This is presented in Table 2 - Indicator of MRD (July 2013 to June 2015).

Strengths

- Constant encouragement and assistance from MRD in the preparation of study documents for submission to research committee and IEC
- Hospital administration provided financial support for all investigator-initiated studies
- MRD provided guidance for research projects including pharma sponsored trials done by consultants and paramedical staff.

Challenges

- To motivate consultants to conduct pharma sponsored trials
- MRD had to train the consultants on Schedule Y and develop additional infrastructure for drug storage, audio-video (AV) consenting, etc.

Table 2: Distribution of indicators of activity phase of Medical Research Department

Indicators	Counts (n) (July 2013 to June 2015)
(a) Number of research training workshops conducted	$n=3$
(b) Total number of research projects	$n=41$
(c) Total number of investigator initiated research projects	$n=24$
(d) Total number of sponsored research projects	$n=17$
(e) Number of consultant/study staff involved per research projects	85/41 ($n=2.07$)
(f) Total number of patient recruited during July 2013 to June 2015	$n=1387$
(g) Average number of patient recruited per study	$n=9.53$
(h) Percentage of patient drop out/lost to follow-up	27/1387 (1.94%)
(i) Total number of protocol deviation reported to ethics committee	$n=31$
(j) Number of manuscripts received for publication	$n=12$

Table 3: Distribution of indicators of activity phase of Hospital Research Committee

Indicators	Counts (n) (July 2013 to June 2015)
(a) Total number of research committee meeting and average per month	23 meetings/24 months (1.04 per month)
(b) Average number of research committee members attended per meeting	98 members/23 meetings (4.26 per meeting)
(c) Number of study projects submitted/reviewed per meeting	49/23 ($n=2.13$ per meeting)
(d) Total number of study projects approved per meeting	41/23 ($n=1.78$ per meeting)
(e) Number of study projects submitted per month	49/24 months ($n=2.04$ per month)
(f) Total number of queries raised per projects	26 queries/49 projects (0.53 per projects)
(g) Average HRC approval time per projects (from date of submission to date of approval)	$n=6.17$ days
(h) Total number of SAE reviewed by Head of institute (chairperson of HRC)	$n=11$

HRC=Hospital Research Committee, SAE=Serious adverse event

Activities of Hospital Research Committee

This is presented in Table 3 - Indicator of HRC (July 2013 to June 2015).

Strengths

- HRC scrutinized all research proposals before moving toward IEC
- Hospital management invested in the development of infrastructure and appointment of additional research coordinators to conduct clinical trial
- Hospital management provided financial assistance to consultant for publication in national and international journals.

Table 4: Distribution of indicators of activity phase of Institutional Ethics Committee

Indicators	Counts (n) (July 2013 to June 2015)
(a) Total number of ethics committee meetings	n=19
(b) Average number of ethics committee members attended per meeting	191 members/19 meetings (n=10.05)
(c) Total number of study projects reviewed per meeting	41 projects/19 meetings (n=2.15)
(d) Total number of study projects approved per meeting	26 projects/19 meetings (n=1.36)
(e) No of study projects submitted per month	41 projects/24 months (n=1.70)
(f) Total number of queries raised per projects	449 queries/41 projects (n=10.95)
(g) Number of scientific queries raised per projects	189 queries/41 projects (n=4.60)
(h) Number of ethical queries raised per projects	213 queries/41 projects (n=5.19)
(i) Number of administrative queries raised per projects	47 queries/41 projects (n=1.14)
(j) Average ethics committee approval time per projects (from date of submission to date of approval)	n=63.3 days
(k) Total number of SAE submitted and reviewed by ethics committee	n=11

SAE=Serious adverse event

Challenge

- HRC felt the need to have legal expert to review the clinical trial agreements and insurance policy from hospital administration perspective
- Monitoring of ongoing research proposal to countercheck study protocol compliance.

Activities of Institutional Ethics Committee

This is presented in Table 4 - Indicator of Institutional Ethics Committee (July 2013 to June 2015).

Strengths

- During IEC meetings, robust discussions were initiated by the external experienced EC members in the view of nurturing the untrained EC members. Trained members encouraged untrained members to fill study assessment form duly highlighting ethical queries
- In due course, more inputs from legal experts, social scientists, and lay person were received.

Challenges

- Internal scientific members were performing more scientific review rather ethical review of the project
- Finding subject experts for project review
- Requirement of training on SAE compensation calculation and recent DCGI guidelines and SAE report review
- Attendance of quorum members
- Monitoring of projects by IEC.

DISCUSSION

After extensive literature search, article on MRD activities and emphasizing steps to establish MRD was not found. A similar study conducted in physiotherapy department, Australia reviewed challenges in setting of research culture as-dedicated equivalent full-time staff to research, supporting staff with joint clinical and academic appointments, research infrastructure and availability of funds.^[3] From the results, it is evident the challenges faced by research department were mainly convincing the trustees for initial investments, no trained manpower, inadequate space, lack of experience and expertise in research projects and heavy workload of consultants. These challenges were circumvent by steps taken by MRD as sensitization through research workshops for consultants, established procedures, and trained support manpower helped to initiate research activities in the hospital and constant encouragement by research coordinator. In addition, the challenges were also overcome with immense cooperation of hospital management for initial investment and appointment of full-time research coordinator.

IEC, on the other hand, had its own challenges. Literature review enlisted challenges which included improper knowledge of appointment of committee members, availability/scarcity of trained legal expert and layperson in the quorum and very few consultant having the research background with no formal training in GCP.^[4,5] Most of the challenges faced during IEC set up remained same however few well trained and experienced IEC external members guided in selection of quorum. Major hurdle of training of new members in SOP and IEC review procedure was accomplished with help of experienced external members. Nonscientific members did not participate actively in discussions during the meetings^[6] but with the help of research coordinator and other external IEC members the nonscientific members were given rigorous training on SOP and document reading process which implemented well.^[7]

Performance indicator of Ethics Committee was reviewed majorly in terms of number of Ethics Committee meeting per month, Number of studies review, Number of queries raised, average approval duration over periods of 2 years since inception. Studies in literature review which evaluated matrices of IRB were done on already established IRB, which can not significantly correlate with this study.^[8,9] However, all our performance indicator were not reviewed separately for clinical and nonclinical studies which limits study. These checklist were prepared considering initial years of establishment including challenges and solutions which are observed similar in literature review.^[10-12]

The unique concept of research committee to govern administrative activities of research projects worked in a better way along with IEC which created phenomenal coordination between investigators, Hospital management and IEC.^[13] To bridge the gap between research committee and IEC, the hospital management decided to include research committee member (Hospital Consultant) in the IEC thereby providing an understanding between both the committees in regards to prioritize protecting the rights and safety of the participants. It also helped investigators in speedy resolution of IEC queries. The MRD has helped in monitoring ongoing research studies to counter check protocol compliance and also uniformly implemented the recent Amendments of Schedule Y including AV consent recording and SAE reporting. MRD ensured quality research procedures; hence, sponsored clinical trials were on a rise and were conducted appropriately leading to more inflow of sponsored study proposals. Looking backward, appointment of full-time research staff, centralized MRD, and the significant role of HRC and HEC helped in the inception of research culture in nonacademic private hospital.

CONCLUSION

Considering evaluation of 41 studies in very first 2 years in research naive nonacademic institute demonstrated successful implementation of trio model of HRC for administrative review, IEC for scientific-ethical review, centralized MRD for coordinating all research projects under one roof which may act as role model for research naive institutes. Performance indicators of HRC and IEC have proved instrumental role in quality review and oversee of research projects. Investigator initiated (59%), and sponsored projects (41%) in all specialties were conducted with immense cooperation from MRD in 2 years. The enabling factors were immense enthusiasm of hospital management, extensive training of consultants and efforts of MRD, and HRC which transformed a research naive hospital to a research institute.

Acknowledgments

We thank the Hospital Management of BhaktiVedanta Hospital and Research Institute.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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