Original Article

Role of accreditation in quality improvement of Institutional Review Board

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Abstract

Aim: The aim of this study was to evaluate the process of accreditation resulting in improvement of the Institutional Review Board (IRB) functioning.

Methodology: Randomly selected projects from years 2007 (before accreditation), 2010 (after accreditation), and 2013 (after reaccreditation) were evaluated to assess parameters, namely, submission of good clinical practices (GCPs), completeness of IRB submission form, fulfillment of quorum, documentation of the declaration of conflict of interests, and submission of the status reports. Compliance to these parameters was compared over a period of 3 years.

Results: A total of seventy projects were evaluated retrospectively. Compliance of the principal investigators regarding submission of GCP certificates increased substantially from 5% to 53.1%. Completeness of IRB forms was 80% in 2007 while it became 100% in 2010 and continued even in 2013. Fulfillment of quorum increased significantly from 35% in 2007 to 100% in 2010 and 2013 after the accreditation procedures. Out of the selected twenty projects (2007), nonfinancial conflict of interest was not declared in all three applicable projects, while of 18 projects (2010), nonfinancial conflict of interest was declared in all three applicable cases. Of 32 projects (2013), nonfinancial conflict of interest was declared in seven out of eight applicable cases. Timely submission of status reports increased from 10% in 2007 to 38.9% in 2010 and 37.5% in 2013.

Conclusion: Accreditation plays a vital role in the improvement of IRB. The policies and procedures formulated and implemented during the process of accreditation resulted in improvement of IRB performance. Continuing training of the IRB and researchers is required to maintain the accreditation.

Keywords: Accreditation, improvement, Institutional Review Board, quality

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INTRODUCTION

Tata Memorial Centre-Institutional Review Board (TMC-IRB) was constituted in 1996 with the aim to formalize and reiterate the institution's commitment toward promoting impeccable scientific and ethical standards in patient care, professional education, research, and community services. In the year 2008, TMC decided to apply for The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) accreditation. The SIDCER, a WHO initiative, is a network of independently established regional forum for Ethical Review Committees.

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IRB accreditation is a systematic and independent examination of the activities and documents to determine whether IRB functions as per the local regulations, guidelines, and standard operating procedures (SOPs). IRB accreditation is a process to assess the performance against a set of standards. The SIDCER accreditation includes measurement of performance on the various criteria such as structure and composition of IRB, adherence to specific policies, completeness of review process, actual and postreview procedures, and documentation and archiving.

Functioning of TMC-IRB till 2008 was as per the manual drafted in 2002. Based on Schedule Y (Drugs and Cosmetics Act 1940 of the Parliament of India, amended on January 20, 2005),[1] International Conference on Harmonization-good clinical practices (GCPs) (1996),[2] Indian Council of Medical Research (ICMR) guidelines (2006)[3] and Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000),[4] TMC IRB established its own SOPs in September 2009,[5] along with the other regulations, such as the Code of Federal Regulations 45 (US-Food and Drug Administration). TMC-IRB was first awarded the WHO-SIDCER accreditation in November 2009 and reaccredited in November 2012 as a part of SIDCER's continuous evaluation process.

The study was performed to evaluate the impact of accreditation programs on the quality of IRB functioning.

METHODOLOGY

The studies submitted to IRB were randomly selected by computer-generated random sampling, and 20% of the total studies discussed every year were studied. Randomly selected twenty projects from the year 2007 (prior to any accreditation), 18 projects from 2010 (after 1st SIDCER accreditation), and 32 projects from 2013 (after SIDCER reaccreditation) were reviewed.

The following five parameters existing in our SOPs (2009) were assessed:

1. Submission of GCP certificate: GCP training is required for principal investigators (PIs) and personnel conducting clinical trials
2. Completeness of IRB form: IRB application needs to be submitted along with the protocol for IRB review by the investigators
3. Fulfillment of quorum during a full-board review
4. Documentation of the declaration of conflict of interest: Any committee member with a conflicting interest in a proposal will have to declare and abstain from deliberations and in the decision-making process on that proposal
5. Submission of continuing review application/status report: Continuing review is to monitor the progress of the study to ensure continued protection of the rights and welfare of research subjects.

Protocol files and the minutes of the IRB meetings were reviewed to:

i. Verify the submission of GCP certificates of PIs
ii. Check the form whether it is duly signed by the investigators and other signatory authorities and mandatory fields are filled
iii. Check whether the quorum requirements as specified in Schedule Y (Drugs and Cosmetics Act 1940) were fulfilled for the protocol under discussion during initial review
iv. Check documentation of nonfinancial conflict of interests such as:
    a. IRB member who is also involved in the research project as PI and co-investigators
    b. IRB member who is related to a researcher whose protocol is under consideration, i.e., spouse/domestic partner and dependent children.
v. Verify timely submission of continuing review application/status report at least annually.

RESULTS

A total of seventy studies reviewed by IRB were assessed. GCP certification was complete in 5%, 5.6%, and 53.1% in 2007, 2010, and 2013, respectively. Almost 80% of the IRB forms were completed in 2007 and reached 100% in 2010 and 2013. The quorum was met for 35% of meetings in 2007 which improved to 100% in 2010 and 2013. Declaration of nonfinancial conflict of interest improved from 15% in the year 2007 to 16.7% (2010) and 21.9% (2013). The timely submission of status reports was 10% in 2007 and increased to 38.9% and 37.5% in 2010 and 2013, respectively. The delayed submission of status reports was 55% in 2007 and reduced to 33.3% in 2010. Thirty-five percent of the status reports were not submitted in 2007 which reduced to 27.8% in 2010 and significantly increased to 62.5% in 2013.

DISCUSSION

IRB holds the responsibility for the protection of the human participants in research. Schedule Y and ICMR guidelines have laid down standards for the functioning of IRBs. IRB accreditation is an intensive, in-depth evaluation of the policies, procedures, and practices of IRB. First, two

parameters, namely GCP submission and completeness of IRB form are related to initial submission, third and fourth, namely quorum requirements and documentation of nonfinancial conflict of interests are related to IRB review process, and fifth is related to the ongoing review. Thus, these five parameters covered the entire review process. The present study showed that accreditation resulted in a significant improvement in the functioning of IRB. While the compliance to the GCP certification increased postaccreditation, yet timely investigators' trainings would be required to further improve the compliance. It was observed that of the seventy studies reviewed, the GCP training certificates of the PIs were not submitted in 51 studies, out of which 17 were prospective interventional trials.

The completion of the IRB forms in terms of filling the mandatory fields and signatures of the investigators and concerned approvals from the departments were checked. There seems to be a remarkable compliance postaccreditation which facilitated the IRB review.

Fulfillment of the quorum is mandated by Schedule Y; however, the quorum was met in only 35% of meetings in preaccreditation period, but dramatically improved postaccreditation. Training of the IRB members and appointment of trained Institutional Ethics Committee staff helped in correcting this lacuna.

IRB needs to ensure that conflict of interests either financial or nonfinancial do not interfere with the review and decision-making.[6] Any member with conflict of interests should declare them and then they would be managed by the IRB. There is no clarity about the financial conflict of interests in an academic setting, although nonfinancial conflict of interests of IRB member, also a part of research team, was not declared in situations where it existed.

IRB is responsible for the continuing review of the progress of the study. The study findings suggest that ongoing review was suboptimal, as there was poor compliance to submission of the status reports by investigators. This prompted a system to send timely reminders to investigators, track submissions, and strict actions for noncompliance. The rate of submission improved thereafter from 2010 to 2013.

Some of the limitations of the present study were that in case of assessing GCP compliance of the investigators, only verification of the GCP training certificates was done, but onsite monitoring needs to be implemented to verify GCP compliance. The completeness of IRB application does not reflect the quality of content/clinical research.[7] While reviewing various conflicts of interests, the only method was reviewing the available documents which may not cover all aspects.

CONCLUSION

Our study showed that the process of accreditation was pivotal in the improvement of the overall functioning of IRBs. The continuing education and training of the IRB members and other stakeholders in its functioning along with researchers mandated by the accreditation programs is deemed necessary for better compliance to regulations and SOPs.

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Conflicts of interest
There are no conflicts of interest.

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