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Research Ethics Board of Health: a seven year review of the only ethics review board in Bhutan

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ABSTRACT

Introduction: Research Ethics Board of Health (REBH), established in 2009, is the only ethics review board in Bhutan. The REBH was certified by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Forum for Ethical Review Committees in the Asian and Western Pacific Regions (FERCAP) in 2010 and recertified in 2013, and it received the Federal Wide Assurance (FWA) from the Office for Human Research Protections (OHRP), USA, in 2010 and in 2013. All researchers conducting health related research in Bhutan have to seek prior ethical clearance from REBH under the requirements of the National Health Policy 2011. The objective of this article aims to describe the performance of REBH, its standard and review procedure. **Methods:** A descriptive study of records and database of REBH from 2009 to 2015. **Results:** As of December 2015, the REBH has received 227 protocols with an average of 32 protocols per year. The median number of days for the initial review was 21 days (Min 0 days; Max 85 days). The median duration for approval of protocols from the date of receiving the application was 48 days. The average number of times the protocols were reviewed before issuing the approval letter was 2. **Conclusions:** There has been a progressive increase in the number of protocols submitted to REBH. This indicated an increasing research culture in Bhutan. It takes about one and half months to get an approval from REBH; therefore, researchers have to consider the time required for ethical clearance process while planning research projects.

Keywords: Ethics Committee; Ethics Approval; Institutional Review Board.

INTRODUCTION

The history of modern healthcare system of Bhutan dates back to 1956 when the first hospital was established at Lhangjophaka in Thimphu[1]. In 1961, the year when the country's first five-years-plan was launched, there were only four hospitals and 11 dispensaries[1]. Since then there has been commendable expansion and development of the healthcare system including research and information management system. The Health Information Unit was established in 1984[2]; Health Research and Epidemiology Unit was established in 1995; and in 2001 Health Research Technical and Ethical Committee was formed. Research Ethics Board of Health (REBH) was established on January 2009 vide an executive order from the Ministry of Health.

The flu surveillance project initiated by the Armed Forces Research Institute for Medical Sciences (AFRIMS) of USA, based in Bangkok, gave the much needed impetus for the institutionalization of the REBH. The Forum for Ethical Review Committees in the Asian and Western Pacific Regions (FERCAP) with support from AFRIMS conducted a training workshop in 2008 to train a group of potential Bhutanese professionals from various backgrounds. The majority of the individuals who underwent the training workshop went on to become board members of the REBH.

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The REBH was certified by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), FERCAP in 2010 and recertified in 2013. It also received the Federal Wide Assurance (FWA) from the Office for Human Research Protections (OHRP), USA, in 2010 and in 2013.

The REBH is composed of 15 members comprising two physicians, one traditional physician, two nurses, one pharmacist, one social scientist, one lawyer, two statisticians, one paramedic, one laboratory expert, one public health expert, one animal health expert, and one lay person. Three of the board members are female and four of them are above 50 years in age while two of them are younger than 30 years.

The board members are appointed for a term of four years and are eligible for re-appointment for two consecutive terms. The Chairperson and Vice-chairperson are elected, through secret ballot by board members, for a term of two years.

The REBH convenes six regular board meetings every year. The first meeting for the year takes place in February and the remaining meetings are scheduled every alternative month. There is a provision of holding an emergency board meeting as well. The list of documents required for proposal assessment are given in Figure 1.

The National Health Policy of Bhutan states, "Any health related research shall comply with the ethical codes of conduct as specified by the Research [Ethics] Board of Health"[3]. Therefore, all researchers conducting health related research in Bhutan have to seek prior ethical clearance from REBH under the

1. In pursuance to Officer Order No. MoH/SEC/33/2014/-15/7021 dated 12th May, 2015, please submit a copy of administrative clearance from the Ministry of Health.
2. Application Form for Initial Review (It can be downloaded from http://www.health.gov.bt/357-2/ Also, it'll be provided on request)
3. Research protocol/proposal including the itemized budget and research project schedule or timeline (final version) – Please write dated version number on it
4. Research/study tools (e.g. final version of questionnaire, forms, guides. etc.) – Please write dated version number on it
5. Curriculum Vitae of all investigator(s).
6. Informed Consent Form and Information Sheet both in Dzongkha and English languages – Please write dated version number on it.

For minor subjects (less than 18 years):

- Informed Assent Form and Information Sheet both in Dzongkha and English languages, and
- Informed Consent Form and Information Sheet both in Dzongkha and English languages for their parents/legal guardians

Submit both hard and soft copies of all above documents to the Secretariat of REBH at Health Research and Epidemiology Unit, Policy and Planning Division – Ministry of Health.

Figure 1. The list of documents required to be submitted to REBH for initial review

requirements of the National Health Policy 2011. The main aim of this article is to describe REBH andits performance from 2009 through to 2015. This article will further promote and ensure the application of ethical principles for the protection of human subjects while conducting research.

METHODS

Design, Data Analysis, and Ethical Consideration The study reviewed the records and database of the REBH maintained with the Ministry of Health from its inception in 2009 through to December 2015.The numbers and proportions were calculated using MS Excel and the time required for review was calculated in SPSS software version 14. The ethical clearance waiver was provided by REBH for this paper as it is not biomedical research involving human subjects.

RESULTS

From January 2009 through to December 2015 the REBH received 227 protocols for ethical clearance. Of these, 77.6% were approved, 20.6% protocols were either withdrawn by the Principal Investigator or were not resubmitted for further review, and only four were disapproved. Plagiarism was the grounds of disapproval for three out of four disapproved protocols. The number of protocols received by REBH has almost doubled in 2015 as compared to previous years (Figure 2).

As shown in Table 1, the median number of days for

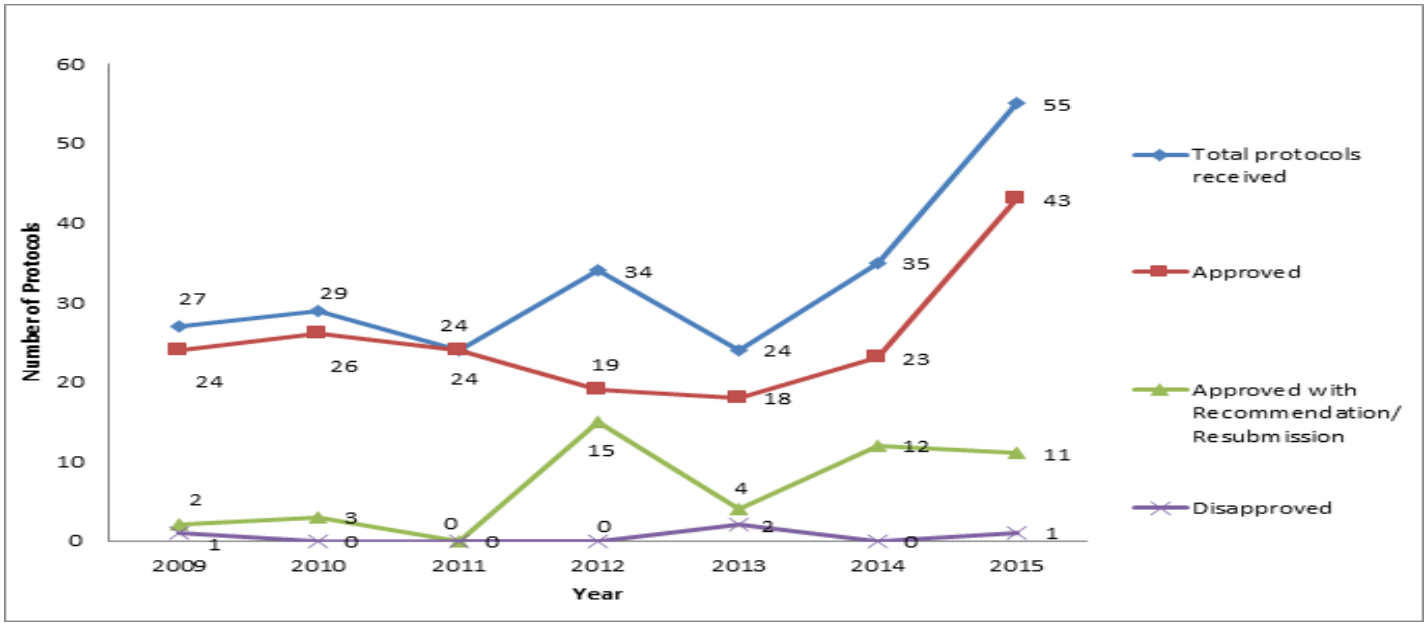


Figure 2. Number of protocols received by REBH from 2009 through to 2015 and protocol review outcomes

initial review of the protocol was 21 days (Min 0 days and Max 85 days). Similarly, the median duration for approval of protocols from the date of receiving the application was 48 days (Min 0 days and Max 315 days).

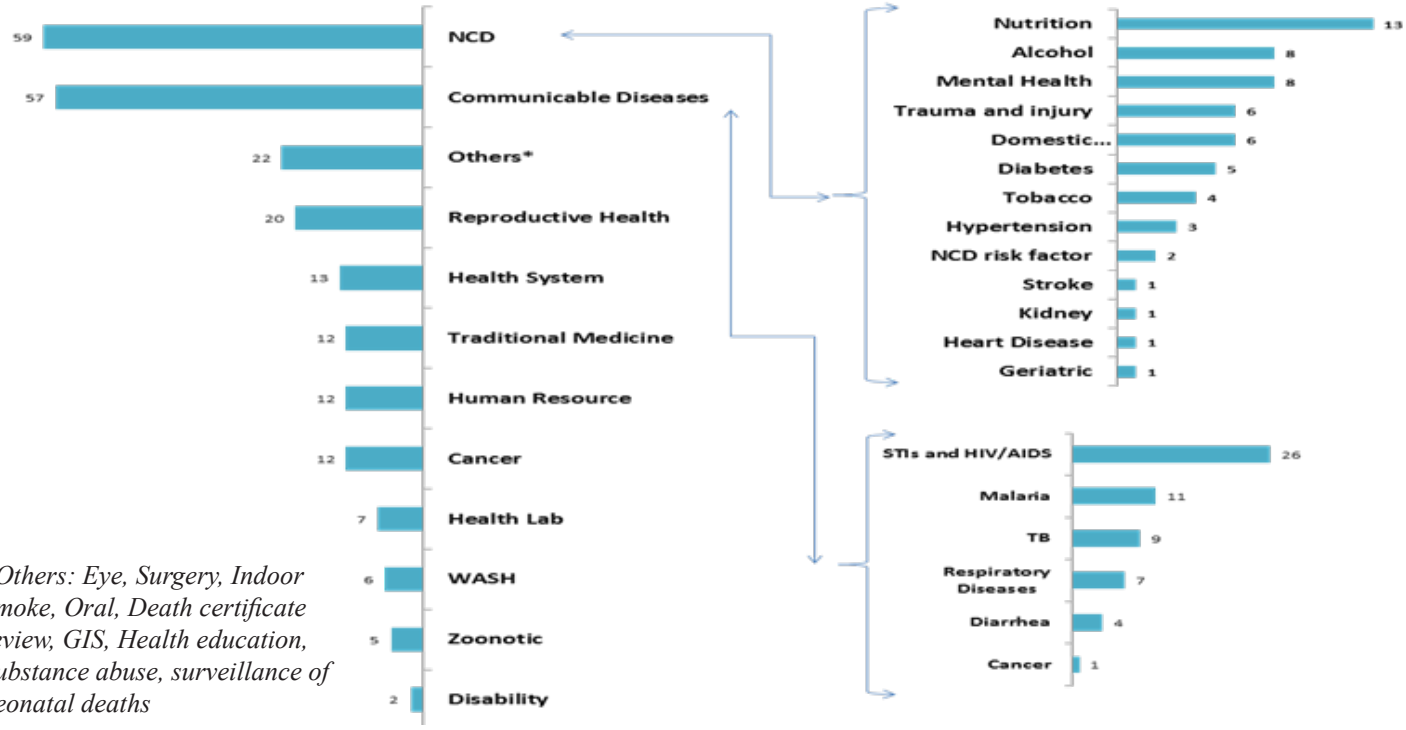
The average number of times the protocols were reviewed before issuing approval letter was 2 (mean, median and mode =2: Min 1 and Max 5).

In the last seven years 20.6% of the protocols were reviewed through expedited process while the remaining articles were reviewed by the full board at least once.

The study designs of almost all protocols (99%) were observational. The maximum number of protocols received by REBH was those related to STIs and HIV/AIDS followed by those related to reproductive health (Figure 3). About 33.5% of the protocols received by REBH from January 2009 through

Table 1. Time required for initial review process and issuance of the final approval from the date of submission of protocols to REBH, 2009 through to 2015

No. of Days	Time required for initial review		Time required for approval	
	%	Cumulative %	%	Cumulative%
<15 days	35.7	35.7	11.6	11.6
15-30 days (1 Month)	30.7	66.4	24.4	36.0
31-60 days (2 Months)	25.9	92.3	20.7	56.7
61-90 days (3 Months)	7.7	100	20.1	76.8
91-120 days (4 Months)			9.8	86.6
121-150 days (5Months)			7.3	93.9
151-180 days (6 Months)			4.3	98.2
>180 days (>6 Months)			1.8	100
Total	100		100	
Mean		27 days		63 days
Median		21 days		48 days
Mode		10 days		16 days
Minimum		0 days		0 days
Maximum		85 days		315 days



**Others: Eye, Surgery, Indoor Smoke, Oral, Death certificate review, GIS, Health education, Substance abuse, surveillance of neonatal deaths*

Figure 3. Number of proposals received by REBH from 2009 through to 2015 by diseases and health areas

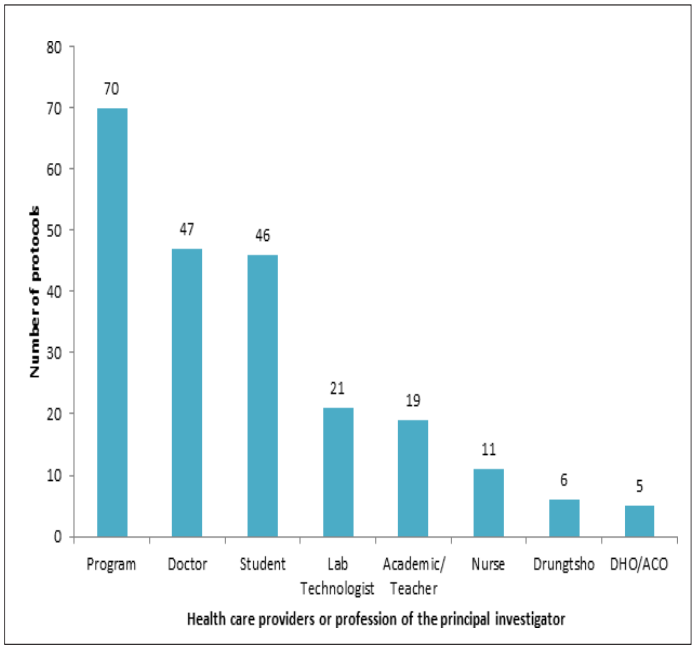


Figure 4. Number of protocols received by REBH from 2009-2015 by health care providers or profession of the principal investigator

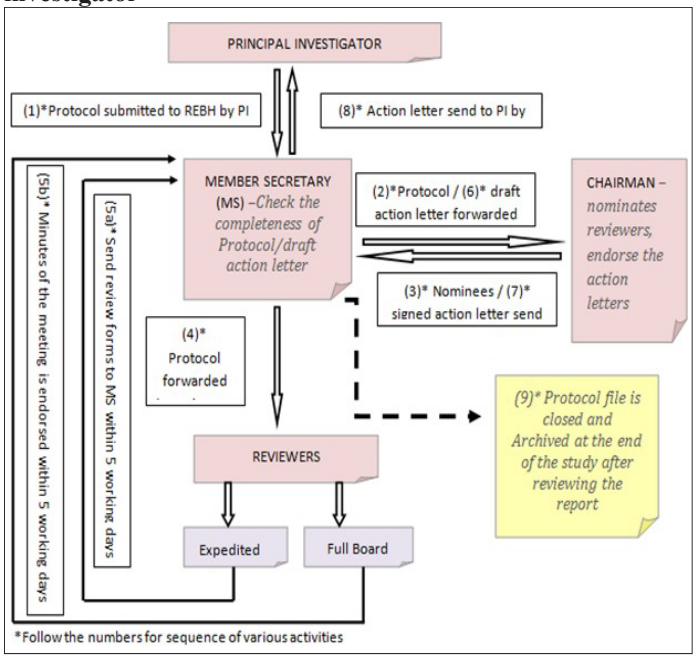


Figure 5. Flowchart of the protocol management and review process in REBH

to December 2015 were master and doctoral degree theses. The maximum protocols were received from program officers, followed by physicians and those working in a laboratory. Very few protocols were received from primary health care providers like Clinical Officers, Health Assistants, and Dzongkhag Health Officers (Figure 4).

The protocol review process is guided by the approved SoP and portocol management as per the SoPs as shown in Figure 5.

DISCUSSION

The progressive increase in the number of protocols submitted to REBH indicates an increasing research culture in Bhutan. The number of protocols received by REBH has almost doubled in 2015 as compared to previous years. The increase was partly attributable to the start of the post graduate residency at the Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB), as nine protocols were from the residents. The university has instituted a mandatory requirement for faculties to conduct research and publish for professional enhancement. In this light, the frequency of the REBH Board meetings was increased to six from four times a year to cater to the increasing number of protocols. The increase in frequency of the meetings is also expected to reduce the time required for review process.

On average, it takes about one and half months to get approval from REBH, therefore, researchers have to consider the time required for ethical clearance process while planning research projects. The researchers also must note that most protocols were approved on second submission while few protocols were approved only after five resubmissions.

According to the Standard Operating Procedures of REBH all documents must reach the REBH secretariat at least two weeks before the scheduled meetings. However, the board has been receiving and reviewing even the protocols that were received on the day of the meeting. As a result, the action letters for 35.7% of the protocols were issued in less than 15 days of submitting the application. For 11.6% of the protocols, even the approval letters were awarded in less than 15 days of submitting the application. However, the minimum review process takes at least two weeks if those protocols which were received during or a few days before the board meeting dates are excluded. The minimum time taken by REBH is comparable to the minimum time taken by the ethics committees in other countries[4–9]. For instance, it is at least three weeks for expedited review and 4-6 weeks for full board review in the Institutional Review Board (IRB) of Cornell University. It takes 2-3 weeks for exempt review, 4-6 weeks for expedited review, and 1 month or more for full board review in the IRB of University of North Carolinaat Charlotte. The mean length of time from submission to approval for simpler protocols was 18-24 days and for more complex protocols was 63 days in the IRB of University of Nebraska–Lincoln[4–9]. The Human Research Ethics Committees of the University of Sydney, Australia, usually take at least 4-6 weeks from submission to final approval and in some circumstances, it will take longer[6].

As required by the International Guidelines for Ethical Committee or Institutional Review Boards, including the World Health Organization's Operational Guidelines for Ethics Committees Reviewing Biomedical Research[10], the REBH consists of scientists and non-scientists, including members from outside the health sector. It has representation from diverse disciplines including the lay person. There is representation of gender as well as of older and younger generations in the board. Some of the board members serve a second term, and board

members have different dates of appointment. These practices facilitate knowledge transfer among the old and new board members and ensure the continuity of the board and its best practices. The SIDCER/FERCAP certification and FWA indicates that the highest standards of ethical review in health research are being met by REBH.

The REBH was established not only to ensure the rights and safety of persons and communities participating in research but also to improve the standard of health research in Bhutan. Given that "scientifically unsound research involving humans as subjects is ipso facto unethical in that it may expose them to risk or inconvenience to no purpose; even if there is no risk of injury, wasting of subjects' and researchers' time in unproductive activities represents loss of a valuable resource"[11], the REBH strives to improve the scientific rigor and methodology besides taking care of the three basic ethical principles, namely, respect for persons, beneficence, and justice in all protocols that it approves.

CONCLUSIONS

On an average it takes about one and half months to get approval from REBH. The REBH has not only ensured the protection of human subjects in line with international standards but has also promoted research culture in Bhutan. The REBH is of an international standard in terms of its structure and composition, adherence to specific policies, completeness of review process, after review process, and documentation and archiving.

There is progressive increase in the number of protocols submitted to REBH, indicating an increasing research culture in Bhutan. The number of protocols received by REBH has almost doubled in 2015 as compared to previous years. In this light, the frequency of REBH board meeting was increased to six from four times a year to cater to the increasing number of protocols. The increase in frequency of the meeting is also expected to reduce the time required for review process.

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AUTHORS CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

MSG: Concept, design, literature search, data collection and analysis, manuscript writing and review.

TD: Concept, design, data analysis, manuscript drafting and review.

DP: Concept, design, data analysis, manuscript drafting and review.

TT: Concept, design, data analysis, manuscript drafting and review.

PD: Concept, design, data analysis, manuscript drafting and review.

Author agree to be accountable for all respects of the work in ensuring that questions related to the accuracy and integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

None

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