ORIGINAL ARTICLE

An Evaluation of the Technical Review Process of the UP PGH Department of Medicine

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ABSTRACT

Background and Objective. The technical review process involves an evaluation of the scientific merits of the research proposal and is a necessary part of the ethics review but can be done separately and ahead of the formal ethics evaluation. The aim of this paper is to determine the efficiency and quality of the technical review process of the Philippine General Hospital (PGH) Department of Medicine Research Office.

Methods. This is a cross-sectional study which involved retrieval of the technical review forms of protocols evaluated in the PGH Department of Medicine from the years 2018-2019, and then an evaluation of these metrics: timelines of the review process indicating efficiency, including time from (1) receipt of submission to receipt of reviewer (secretariat efficiency); (2) receipt of reviewer to first decision (reviewer metric); (3) initial receipt to final decision (total review time); and (4) number of re-submissions. To evaluate the quality of the reviews, the specific review findings in each part or section of the protocol were also extracted.

Results. In the years 2018-2019, a total of 199 protocols underwent technical review, with one protocol having no further data after the submission so only 198 proposals were analyzed. Majority of the protocols or 139/198 (70.2%) were submitted only once and were approved without comments, while the remaining 59/198 (29.8%) were submitted twice for technical review (mode of 1, mean of 1.32). The protocols were sent to the reviewers within the same day of receipt 100% of the time. The time from receipt of submission to receipt of reviewer was within the same day and the time from receipt of reviewer to first decision (mean, standard deviation working days) was 10.52, 8.54 days, range 0-51 days. Around one-fourth (21.51%) of the protocols were returned to the secretariat beyond the 14-working day deadline. The time from second review of technical reviewer to return to secretariat was a mean, SD of 6.72, 6.45 days, with a range of 1 day to 36 days, and time from initial receipt to final decision was a mean of 16.16 days, SD 18.3 days, range 0-111 days. The most common reason for the delay was the failure of the author to resubmit the paper for the second review in 17/23 (74%), while the other reason was the long duration of the initial review by the reviewer in 6/23 (26%). Half of the protocols (49.5%) were returned without comments. Majority of the comments were on the methodology.

Conclusions. The technical review process is generally efficient with each step within the acceptable timelines. However, for 12% of the protocols, the over-all review process was still prolonged (>28 working days) because of the failure of the author to submit the paper for the second review in 74% of cases, and the long duration of the initial review in 26% of papers.

Keywords: technical review, quality assessment, audit

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INTRODUCTION

The Philippine National Ethics Research Guidelines of 2017 define "research" as an activity that aims to develop or contribute to knowledge that can be generalized (including theories, principles, relationships), or any accumulation of information using scientific methods, observation, inference, and analysis.[1] Any research, especially health research and those that involve human participation undergoes a process

of review and approvals prior to implementation. In UP Manila, the first tier is a technical review which is done in the department from which the investigator comes from, followed by a centralized ethics review by the UPM Research Ethics Board.[2] (Appendix: Flowchart for Technical Review)

The technical (or scientific) review can be facilitative of the ethics review, as the first part of the ethics review involves a determination of the scientific validity of the research question (NEGHR 2017).[1] The determination of the paper's scientific validity involves protocol-related issues that have to do with the basis and relevance of the research question, including the review of the pertinent literature; and evaluation of whether the design, methodology, and data collection supports the objectives of the study. Research ethics has several components but foremost among these is social value, which can only be realized if the study is scientifically valid.

There are many publications on best practice recommendations for ethics reviews but hardly any for the scientific review process. The researcher has the following responsibilities with regard to the research ethics review that also touch on the scientific review: (1) develop scientifically sound research proposals; (2) understand and apply research ethics standards; (3) ensure that applications are thorough and complete; and (4) be responsive to requests for revision and clarification.[3] While these are the responsibilities of the researcher, the administrators need to ensure that they have oversight on the researchers and that institutional requirements are applied. Since the protocol will be carried out in the department, the scientific review is first carried out in the same department prior to a centralized ethics review.

Therefore, an efficient and effective technical review process can potentially ease the process of ethics review. A review of published literature in the Philippines did not yield any previous researches on this topic. This study is relevant because there has been no formal evaluation of the technical review process. The Department of Medicine yearly receives over 100 papers for registration and review, and given this volume of protocols, there may be a need to streamline and improve our processes. We need to evaluate both the efficiency of the process of technical review as well as its effectiveness e.g., the content or validity of the review, in order to improve on this process. The scientific review follows a systematic process by which the "expert" answers guide questions that have to do with the parts of the protocol. Hence, it is expected to be a relatively quick process so that the turn-around time for the review would be two weeks or less. An evaluation of the quality of the review is as important as an audit of compliance with timelines.

The primary objective is to assess the efficiency of the technical review process at the UP PGH Department of Medicine Research Office. The specific objectives of this research include to determine the timelines of the review process indicating efficiency, including mean time (mean working days) from (1) receipt of submission to receipt of reviewer (secretariat efficiency); (2) receipt of reviewer to first decision (reviewer metric); (3) initial receipt to final decision (total review time); and (4) number of re-submissions. To evaluate the quality of the reviews, we also summarized the specific review findings in each part or section of the protocol and the common findings that cause delays in the technical review process as defined by a protocol review longer than 14 working days.

MATERIALS AND METHODS

Design

Cross-sectional analytic study

Setting

The Philippine General Hospital is the national university hospital of the Philippines. The Department of Medicine is composed of two wards with a total of 106 beds and one medical intensive care unit with a 12-bed capacity. Its manpower is composed of 137 consultants of various specialties and trainings, with 116 training fellows and 67 residents, along with nurses and nursing staff, all of whom are encouraged or required to do research.

Inclusion Criteria

1. All research protocols of the consultants, fellows and residents-in-training that underwent scientific or technical review in the Department of Medicine
2. Protocols should have been reviewed (but not necessarily completed) from January 1, 2018-December 31, 2019.

Exclusion Criteria

1. Those from interns rotating in the department
2. Those from other individuals who wanted to do research in the department
3. Those which were never submitted for ethics review

METHODS

The list of all research protocols that underwent technical review were generated from the electronic file of the Department of Medicine Clinical Research Division from 2018-2019, and the following data were extracted from each submission including timelines of the review process indicating efficiency, including time from (1) receipt of submission to receipt of reviewer (secretariat efficiency); (2) receipt of reviewer to first decision (reviewer metric); (3) initial receipt to final decision (total review time); and (4) number of re-submissions. To evaluate the quality of the reviews, the specific review findings in each part or section of the protocol were also extracted.

A research assistant who is not connected with the Department of Medicine Research office was trained by the investigator and co-investigators to extract the data from the technical review forms as outlined. Each record or protocol

was given a study code to record the data enumerated above, but the names of the investigator(s) nor the title of the research will not be collected. Data was then summarized into data tables and graphs.

Numerical data such as the review metrics were summarized using descriptive analysis of the measures of central tendency such as mean, median, standard deviation, and range. Qualitative data were summarized using percentages and frequency distributions. The specific review findings will be summarized according to themes and specific recommendations will be made regarding these.

This study protocol was submitted for ethics review to the University of the Philippines-Manila Ethics Board (UPM REB) prior to any data collection and was approved on an expedited basis with registration code 2020-352-01. This study was done in full compliance with the Data Privacy Act of 2012 and the (Philippine) National Ethical Guidelines for Health and Health-related Research (2017).

RESULTS

A total of 199 protocols underwent technical review in the years 2018-2019, with one protocol having no further data after the submission so only 198 proposals were analyzed. In 2018, 91 protocols were received, while 108 were received for review in 2019. Majority of the protocols or 139/198 (70.20%) were submitted only once and were approved without comments, while the remaining 59/198 (29.8%) were submitted twice for technical review (mode of 1, mean of 1.32). Most of the protocols were from fellows-in-training at 125/198, followed by nearly equally by faculty and residents at 35 and 34, respectively, with interns contributing 4 protocols (Table 1). The distribution of protocols according to divisions is also listed in Table 1 with the most number from the Division of General or Adult Medicine with 32/198 (16.16%) which included the researches of the residents-in-training.

Table 1. Distribution of Research Protocols According to Characteristics of Investigators and Metrics (January 2018- December 2019)

Profile of Research Protocol	Results (N=198)
Designation	
Intern	4 (2.02%)
Resident	34 (17.17%)
Fellow	125 (63.13%)
Faculty/consultant	35 (17.68%)
Distribution according to Division	
Allergy and Immunology	4 (2%)
Cardiology	11 (5.56%)
Dermatology	17 (8.58%)
Endocrinology	10 (5.05%)
Gastroenterology	8 (4.04%)
General medicine (includes residents)	32 (16.16%)
Hematology	17 (8.59%)
Infectious Diseases	18 (9.09%)
Medical Oncology	22 (11.11%)
Pulmonary medicine	23 (11.61%)
Renal	13 (6.57%)
Rheumatology	23 (11.61%)
Time from receipt of submission to receipt of reviewer (secretariat efficiency)	0 days
Time from receipt of reviewer to first decision (reviewer efficiency)	Mean 10.52 days, SD 8.54 Mode 10 days Range 0–51 days
No (%) of protocols beyond 14 days from receipt to first decision	38/198 [19.2%]
Disposition or decision after first review	
Approved on first review	133 (67.17%)
With minor revisions	52 (26.26%)
With major revisions	7 (3.53%)
Disapproved	0 (0)
Discontinued after approval	6 (3.03%)
Time from receipt of reviewer to decision (second review)	Mean 6.72, SD 6.45 Range 1–36 days
Total time from initial receipt to final decision	Mean 16.6 days, SD 18.3 Range 0–111 days

Table 2. Findings Found in Specific Sections of the Protocols in the Technical Review, N=198

Parts of the Protocol	Findings (N, %)	
	With comments	No comments
Comments on the Introduction, title, background	53 (27)	145 (73)
Materials and Methods	57 (29)	141 (71)
Site is not appropriate		
Outcome measures not specified		
Study design not appropriate to objectives		
Faulty inclusion/exclusion criteria		
Sampling design is wrong		
No (or faulty) sample size calculation		
Data Analysis	6 (3)	192 (97)
Inappropriate data analysis		
Statistical analysis is not appropriate to objectives		
Dummy Tables and Graphs		
Administrative Issues	0 (0)	198 (100)
Budget given or not well written		
Duties and responsibilities		
Timelines/No Gantt chart		
References	1 (0.5)	197 (99.5)
Other findings	2 (1)	196 (99)

These are the main results of the study (efficiency metrics). The protocols were sent to the reviewers within the same day of receipt 100% of the time which implies that generally the secretariat is efficient in ensuring that the protocols are decked and sent to the faculty reviewers in a timely manner. The time from receipt of submission to receipt of reviewer was within the same day and the time from receipt of reviewer to first decision (mean, standard deviation working days) was 10.52, 8.54 days, range 0-51 days. Around one-fourth (21.51%) of the protocols were returned to the secretariat beyond the 14-working day deadline.

Of the 59 protocols that had minor or major revisions, two were not resubmitted and the remaining 57 underwent a second review. The time from second review of technical reviewer to return to secretariat was a mean, SD of 6.72, 6.45 days, with a range of 1 day to 36 days, and time from initial receipt to final decision was a mean of 16.16 days, SD 18.3 days, range 0-111 days. While the mean time for the second review is less than a week, 23/57 (40.35%) of the papers that underwent a second review had a total time of review from first submission to final disposition of more than 28 days. The most common reason for the delay was the failure of the author to resubmit the paper for the second review in 17/23 (74%), while the other reason was the long duration of the initial review by the reviewer in 6/23 (26%).

The next part of the results is focused on the specific review findings in each section of the protocol. Half of the protocols or 98/198 (49.5%) were returned without comments. Majority of the comments were on the methodology. (Table 2)

Approximately 27% (53/198) of the papers had comments in the title, introduction, background or review of literature. Of those which had comments, there are typically single comments centering mostly on these three mains points: (1) improving the title to be reflective of the objectives or intent of the study, or ensuring that the design as written in the title is correct, (2) the review of literature or background is incomplete and does not describe adequately the state of knowledge on the issue and the research gaps including local or Asian literature; and (3) the objectives which need improvement because they are either overlapping, redundant, incomplete, not consistent with the design or methodology, or needs to be stated as measurable targets rather than outcomes. There was one comment that said that the review of literature is too lengthy with irrelevant sections.

For the next part, 57/198 (28.8%) of papers had comments in the materials and methods section. Compared to the introduction, those who gave comments in this section typically had multiple comments to clarify the following: (1) study design which are either faulty or inappropriate for the study objectives, with the reviewer recommending a more appropriate design than what was written; (2) description of the study population (Inclusion and exclusion criteria) specifically clarifying the criteria used for selection or exclusion; (3) sampling design; (4) study procedures, clarifying the specific methods of data collection or use of questionnaires (self-administered or investigator-administered), algorithms for decisions on outcomes, what comparators will be used and other study-specific methods, and (5) outcomes, with questions on the definitions or criteria for some of the outcomes, or determination of outcomes for those with incomplete data. There were only two comments regarding the sample size, asking for clarification for the basis of the sample size or an increase in the sample size given

the number of variables to be investigated. Likewise, there were very few questions regarding the data analysis or even the use of statistical tests for analysis.

The next section in the technical review (form) is on data analysis, including statistical analysis and the use of dummy tables and graphs. There were very few comments on this portion as only 6/198 (3%) of the protocols had any. These comments were mostly recommending clarifications on how outcomes will be computed, the variables which will be analyzed, and the manner of data recording, analysis, recording and reporting rather than questions on the actual statistical design or analysis.

Likewise, an important part of the technical review is an evaluation of the logistical or administrative aspects of the research including the budget, timelines which are spelled out in the Gantt chart, and a listing of the members of the research team and their duties and responsibilities. There were no comments at all on this section. Finally, for the references, there was only one comment that the citations need to be revised. Other than these comments, there were two reviewers who recommended that the protocols need to be corrected for spelling and grammatical errors, including the proper use of "tenses".

DISCUSSION

The technical review process is a necessary step prior to ethics review of research protocols to ensure that the research project has social value and significance. The responsibilities of the principal investigator (PI) and the department chair or the research office and their technical reviewer are well elaborated in the manual of the Research Implementation and Development of the UP College of Medicine.[4] It is clear from the manual that it is the responsibility of the PI to submit the research protocol and the filled technical review form to the department where he belongs, in a timely manner. This includes the re-submissions of protocols after modifications following the first review. The results of our paper show that there are lapses in the responsibilities of the PI for the second review as 40% of papers that underwent a second review had a total time of review from first submission to final decision of greater than 28 days. The most common cause of delay was the failure of the author to resubmit the paper for the second review in 17/23 papers or 74%. There was even one protocol which was resubmitted for the second review after 36 days.

The RIDO manual also describes the responsibility of the UPCM Department Chair or its authorized department member to assign a roster of Technical Review Board (TRB) members.[4] In the Department of Medicine, this responsibility is given to the Medicine Research Office, where the research assistant (RA) is supervised by the Vice Chair for Research. This responsibility of decking the protocol to a specific reviewer is generally efficient as the protocols are given to the assigned reviewer within the same day, or on Fridays or days followed by holidays, within the next working day.

How about the technical reviewer? His main responsibility is to evaluate the relevance and scientific merit of the research protocol and reporting his findings using the prescribed Technical review form. Whenever the paper need to be modified, it is also the responsibility of the reviewer to specify his comments.[4] For the first responsibility of accomplishing and returning the technical review form, the TRB reviewer is also generally efficient as the mean time from receipt of the protocol to the first decision is evaluated. The mean time is 10.52, SD 8.54 days with the mode likewise of 10 days. This is well within the 14 working days that is given for the review. However, nearly 20% of all protocol were returned beyond the 14-day deadline for the review, with one paper returned to the secretariat of the Department of Medicine Research Office after 51 days. The technical review cannot be facilitative of the ethics review when the timelines are too long especially in consideration that around one-third of all protocols needed to be rewritten due to major and (mostly) minor revisions recommended by the reviewers.

For the second responsibility of the TRB reviewer to give comments for improvement of the paper, around half of the protocols were returned without comments. This current study did not evaluate whether this finding affected the ethics review process but it is well known that the greater majority of protocols are returned for modification after being submitted to the UP Manila Research Ethics Board. It is possible that one reason for the many comments during the ethics review was because the research protocols were not adequately evaluated during the technical review. Of those which were returned with comments, majority of the comments were on the introduction and the materials and methods. There were hardly any comments on the data analysis or the statistical design (only 6/198 or 3%), and none at all for the logistical or administrative issues such as the budget, duties and responsibilities of the study team, and the study time lines. It is not known whether the reason for the sparse comments on the data analysis or the statistical tests used for analysis is due to the unease of the reviewers with this part of the protocol, or the lack of training of the TRB members on these aspects of research.

CONCLUSION

The technical review process is generally efficient with each step within the acceptable timelines. However, for 12% of the protocols, the over-all review process was still prolonged (> 28 working days) because of the failure of the author to submit the paper for the second review in 74% of cases, and the long duration of the initial review in 26% of papers. Majority of the protocols were also returned without comments. This paper has identified gaps in the technical review process which need to be addressed, and hopefully will facilitate the succeeding steps of ethics review.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

All authors declared no conflicts of interest.

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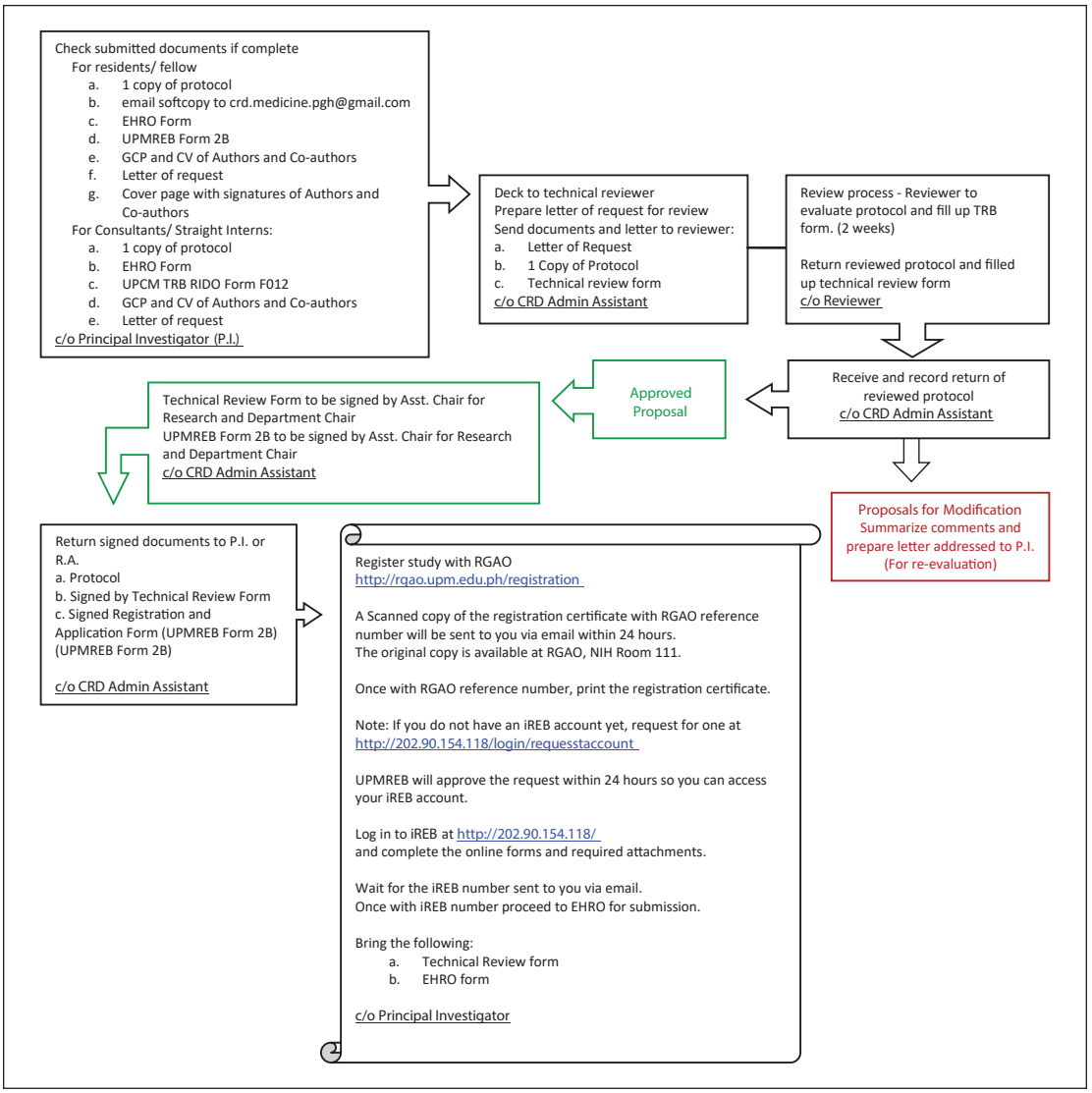
APPENDIX



Appendix. Flowchart Technical Review Board and RGAO Registration Process.

Source: Process Flow for Technical Review and RGAO Registration Clinical Research Division, UP PGH Department of Internal Medicine. 2018.Unpublished.