Research Ethics Committees in Manila Schools: Exploring the Reasons for its Non-Existence

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ABSTRACT

Objectives. This study aimed to explore the reasons behind the "resistance" of higher education institutions (HEIs) located in the south Manila area in creating research ethics committees (RECs). It also examined the proportion of researches in these HEIs with human participation.

Methods. Research directors underwent key informant interviews while faculty researchers participated in focus group discussions. Universal sampling was employed on all researches in the schools to determine the proportion with human participants and to know if they are ethically "high risk" or "low risk" in terms of the participants' involvement.

Results. We included ten higher education institutions in this study. Research directors and faculty researchers agreed that their school should have a REC and that studies should undergo ethical evaluation before commencement of data collection. Half of all researches were found to have human participant involvement and, after developing a tool to determine the risk level to participants, this study found that ethically high risk researches are found to represent 10% as a proportion of the total researches done in the schools.

Conclusion. Almost all respondents in this study agreed that RECs should be created; however, there are financial challenges that schools face in establishing RECs.

Keywords: ethics review, Manila schools, ethics committee, ethics committee accreditation, higher educational institutions

INTRODUCTION

The role of ethics committees in the social sciences has been met with resistance by some researchers. Issues include imposition of silly restrictions by ethics committees, ethics review being a solution in search of a problem, lack of expertise,[1] the "ethics creep" and increased bureaucratization of research ethics board/institutional review boards.[2,3] However, the significance of its function in protecting research subjects is shown by the establishment of research committees all over the world, in regulatory bodies and leading universities.[4-10]

The Philippine National Health Research System (PNHRS) Act of 2013 (Republic Act 10532) institutionalized a memorandum of understanding among three government agencies (Department of Science and Technology [DOST], Department of Health [DOH] and the Commission on Higher Education [CHED]) and a component unit of the University of the Philippines System, the University of the Philippines Manila (UPM). The essential mandate of these four institutions in this law is to work towards "improving the health status, productivity and quality of life of Filipinos."[11]

Paper presented in the Philippine National Health Research System Pre-Conference The Need for Ethics Review in the Health and Social Sciences: Implications in South Manila Colleges and Universities on August 13, 2019, at the Limket Kai Hotel, Cagayan de Oro City.

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When PNHRS was still a bill in congress, the four agencies created the Philippine Health Research Ethics Board (PHREB) under the Department of Science and Technology in 2006, to "ensure adherence to the universal principles for the protection of human participants in research."[11] In line with this, PHREB is mandated to monitor and evaluate the performance of research ethics committees (RECs) in accordance with PHREB approved procedures, among other things. To this end, PHREB accreditation is a requirement for all RECs.[11]

PHREB accreditation has three levels, which are indicative of both the type of research and the degree of risk involved in the protocols/proposals reviewed by the RECs. Level 1 accredited RECs review researches with minimal risk to participants. Level 2 accredited RECs review all types of researches except clinical trials required for Food and Drugs Administration (FDA) registration of new drugs. These may entail more than minimal risk to participants. Post-marketing studies may be reviewed by Level 2 RECs. Level 3 accredited RECs review all types of researches including studies required for FDA registration of food, drugs and devices. Level 3 RECs may be invited by the FDA to conduct regulatory reviews on behalf of the latter and these accredited RECs shall comply with ICH-GCP standards.[11]

The regulatory function of PHREB has been iterated by CHED through several memoranda for immediate compliance by schools of higher education and was disseminated in all 2396 higher educational institutions (HEIs) in all regions in the Philippines.[12] The first one endorsed[13] a DOST memorandum in 2007 urging institutions that conduct biomedical and behavioral researches to establish review committees to ethically evaluate and monitor researches involving human participants.[14] The second one is part of a joint memorandum by the four PNHRS agencies in 2012 requiring all health researches involving human subjects to undergo ethical review and clearance before implementation to ensure the safety, dignity and well-being of research participants.[15] The third one was in 2015 that directed private and public higher educational institutions to register and accredit their ethics review committees with the Philippine Health Research Ethics Board (PHREB) by December 30, 2015.[16]

Despite these memoranda, only a few HEIs have formed their own RECs. The question of resistance to the establishment of RECs and reviewing protocols, has cropped up again. If so, what are their reasons? How many researches in HEIs, in the social sciences and otherwise, involve human participants that would require REC evaluation and clearance? The answers to these are the onus of this study.

Once answered, the CHED, the PHREB and the HEIs will hopefully assist each other to come up with good policies and solutions in the establishment of RECs in the academic milieu.

MATERIALS AND METHODS

This study aimed to explore the status of ethics reviews of researches conducted in higher education institutions that belong to a Securities and Exchange Commission-registered, non-government organization with 12 member schools (public and private colleges and universities) located in the south Manila area.

Inclusion criteria in this study are: 1) school should not have an accredited research ethics committee, and 2) administration of the school should give consent. The study protocol was presented to a meeting of the board of trustees of the said organization and was given permission subject to acquiescence of their research directors.

There were several methods of inquiry that were engaged in a multimethod procedure: (1) research directors of these schools underwent key informant interviews (KII); (2) faculty researchers were asked to participate in focus group discussions (FGD) per school as they share a commonality of belonging to one school; and (3) researches were examined to determine the proportion that involved human participants, to know if they are "high risk" or "low risk" in terms of the participants' involvement (see Tool Development). Total enumeration as a form of sampling was done and therefore all researches were included.

Two schools were excluded since one school declined to participate, and another school, the school of the principal investigator, already had an ethics review committee. Ten schools were included in the study and informed consent forms were sent to the research directors as well as the faculty researchers. The research directors were advised that the primary investigator, the sole interviewer, would ask them to estimate the proportion of researches with human participants, their belief in ethical clearances of researches with human participants, and to reflect on the challenges in the creation and accreditation of their ethics committees.

Faculty researchers who were included in the FGD were deemed homogenous and fulfilled the operational definition of a faculty member who had completed a research work in the last three years or two research works in the last four years before the study. They were identified by their respective research offices. They were given one week to respond. Those who consented were given the day and time as to when the primary investigator, again the only one who did the facilitation of the group discussions, would be visiting their schools to conduct the group discussions. The faculty researchers were asked regarding the estimated proportion of their researches involving human participants, familiarity with ethics review committees and the perceived challenges in submitting research proposals to such committees and belief that a research with human participants should undergo clearance with an ethics committee.

Both the KII and the FGD were done sequentially in one day per school by only one interviewer/facilitator. Each form of data collection took about 45 mins. The KII for the

research directors was conducted first in a room separate from where FGD would be done. Eligible faculty who agreed to participate in the FGD and who were free at the designated time the facilitator was present were then interviewed as a form of purposive sampling.

The study followed the basic qualitative approach where authors individually immersed themselves in analyzing the data. The authors utilized the procedures proposed by Watkins (2012) for data analysis in which the interpretation of transcripts is aligned to the objectives of the study. The three authors familiarized themselves with the transcripts and independently developed a bank of codes and compared them with each other. Any differences were resolved through discussions. The lead researcher organized the coded data into themes which the two other authors reviewed; again, any differences were resolved through discussions. After the review, the themes were then named.

For the document reviews, two research assistants from each school research office examined the school's completed researches, which were de-identified, and determined if they were high risk or low risk to research participants. These research assistants underwent a rigorous two-week training using an operationally defined matrix to determine the risk of researches to participants. This training included a workshop in which trainees were required to present their evaluation of randomly completed researches. The number of researches were complete enumeration/universal sampling of the researches in the schools, in the recent two years duration, which included the theses/dissertations of undergraduate and graduate students together with the faculty researches. Every rating done was an agreement between the two research assistants.

The study protocol underwent and complied with the requirements of the University of the Philippines Manila Research Ethics Board.

Tool Development for Risk Evaluation

A tool was developed to determine the level of risk to participants of a research when they participate in a study.

The researches were first determined if they involved human participants. These may have been observational studies in the form of interview, survey, focus group discussions, observations or retrospective review of participant records; or interventional/experimental methods in the form of clinical intervention/treatment intervention (e.g. administration of herbal medication or nutritional supplement), implementation of a health program or educational program or psychological intervention and/or psychotherapy.

The risk evaluation scale was crafted to ascertain if the researches in the schools were ethically of high or minimal risk in nature. This included determining the nature of harm and the extent of harm. The nature of harm may be psychological, physical, legal, social and economic. The extent/magnitude of harm was divided into five scales which later became three: great extent, moderate extent, little extent. A rubric was developed to define each of these extents of harm.

The rubric guided the evaluators in assessing the research protocol for the level of harm that indicated if the research procedures put the participants at minimal risk or if risks were greater than minimal. The researches were also given a numerical value based on the likelihood or certainty of the occurrence of harm. For probability, the rating ranged from high (3), medium or moderate (2), to low probability (1).

To determine the extent of risk, the magnitude was multiplied with the probability. For instance, if the rating for the magnitude of psychological harm was 1 and the rating for probability was 2, the risk assessment for psychological harm was 2. The highest possible score for each nature of harm was 9 (magnitude 3; probability 3) while the lowest possible score for each nature of harm was 1 (magnitude 1; probability 1). The level of harm was considered minimal risk when the rating for magnitude and probability in each nature of harm were both equivalent to 1. This suggested that the extent of harm was minimal and with a low likelihood that it will happen. When the rating for magnitude or probability had a value of 2 in any of the nature of harm, the level of harm was already considered beyond minimal risk because the extent of harm was moderate and with a probability that it will happen. The research protocol was considered high risk when the rating for magnitude or probability in any of the nature of harm was equivalent to 3 as this meant that the harm was perceived to be of great extent or was very likely to happen.

RESULTS

Findings are to be presented in three sections: 1) interviews with the research directors and the group discussions with the faculty researchers. 2) proportion of researches with human participants, 3) categorization of researches with human participants to low risk and high risk.

Interviews with Research Directors and Focus Group Discussions with Faculty Researchers

The ten research directors had a mean age of 49 years old and 80% (8/10) were female. They stated that the researches in their schools were a mix of those with and without human participants. All schools had researches with an estimated 50% to 95% human participants, half of them (5/10) saying that at least 90% of their researches involved human subjects.

Three research directors did not know that it was mandatory for research proposals with human participants to undergo an ethics committee clearance as per issuance of the Commission on Higher Education (CHED) memoranda in 2012 and 2015. Although seven believed that all researches should be ethically cleared by an ethics research committee, the other three believed that the researcher, if he is a faculty, or an adviser of students who were doing research, could decide if their researches should undergo ethical clearance

even if their study involved human participants. The logic of the latter was that they would know the methods in the study and whether they entail minimal risk to the participants or not.

Four out of the ten schools established ethics committees by 2017 although only two had their ethics committees accredited (one of which admitted that their committee was "not active") by the Philippine Health Research Ethics Board (PHREB). The other two had each a research committee but did not have it accredited because one had no funding and the other was still "polishing" their standard operating procedures (SOP), a requirement of PHREB. Funding was also required to create a physical office for the committee, for the continuing education of the members of the committee and to compensate reviewers, all of which are required by PHREB. The rest of the member schools (6/10) had no research ethics committees, the reasons of which include; no budget or too big a budget requirement (3/6); two schools (2/6) had money but the groundwork of writing the SOP was a long process. No administrative support in terms of funding was a pervading reason for not establishing an ethics committee.

Themes that evolved from the KII included (1) ethical approval of research; (2) creation of RECs; and (3) accreditation of RECs.

Ethical approval of research suggested that one of the roles of the research director was to decide if a research should undergo ethical clearance or not. Furthermore, ethical approval is a requirement for journal submission.

Another theme pertains to the creation of RECs. The research directors described the RECs as mandatory committees for research production and that the hindrance to the creation of RECs is the increased faculty loading and need for renumeration of its members.

Accreditation of RECs also had hindrances as this theme described the technical problem of making the standard operating procedures required by PHREB and the monetary requirement for the maintenance of an additional office in the institution.

Fifty-two faculty researchers participated in the focus group discussion. The respondents' age ranged from 40 to 50 years and 24 were female. All except one (51/52) attested that the researches they do almost always involve human participants and were mostly social science researches.

There were several themes that evolved from the FGD that included (1) ethical approval of research; (2) mandate of RECs; and (3) creation of their school's RECs.

Ethical approval of research implies that the research is of good quality if it has been cleared by an ethics committee. This theme also suggested that ethical approval is a requirement for submission in a journal. The ethical approval may be done by the advisor or administrator. The faculty researchers opined that the mandate of RECs includes evaluation of the technical soundness of the study and plagiarism check to monitor the copy-paste culture. The paper should also be checked to conform with the Data Privacy Act. Another mandate of RECs is that members should undergo training on ethics research so that they know how to evaluate studies. Protection of participants was also a mandate in questionnaires for evaluation so that the questions are acceptable to participants and they will not experience anything emotionally painful.

The creation of RECs was also a theme that surfaced and was said to be dependent on the research culture of the school as only a few faculty do research, so only a few know the need for research ethical clearance. Some said that the technical and ethical evaluation are sometimes done by the research office, which would duplicate the work of the REC. Finally, the creation of RECs was the decision of administrators, who may lack knowledge that it is needed in research.

Almost all said that they were familiar with research ethics committees. A few said they "just have an idea" of what it is. Only a few of the respondents had submitted to a research ethics committee. For those who have submitted, half said that their experience was satisfactory; the other half said the decision was too slow.

When asked if all researches should undergo research ethics review, most faculty researchers agreed, especially for those with human participants. The reasons given why researches should undergo ethics review include: quality control, to be in consonance with the Data Privacy Act (a law enacted in the Philippines only in 2012) and to prevent plagiarism. Some said that students should have their studies ethically evaluated so that they would know the risks of their study to participants. Some said the dean of a college may decide whether a paper may be submitted to the REC or to forego the submission.

Characteristics of Researches with Human Participants

Fifty two percent (52%) of all researches in the ten schools involved humans as participants. Eight out of ten schools had human participants in more than half of their research (Table 1) ranging from 58% (School 3) to 98% (School 5), with four schools that had 90% or more of their researches with human participants. Only two schools (Schools 2 and 6) had below 50%. Although the faculty and the graduate program researches of School 2 when combined had more than 90% with human participants, the bulk of the research was in the undergraduate program involving electronics and electrical experiments. On the other hand, while the bulk of the research in School 6 were also from the undergraduate programs, total proportion of research with human participants was only 28%.

School 7 had the highest proportion (29%) of their research with human participants in the high risk category, especially among graduate students (83%) (Table 2). Overall, 10% of all research with human participants from the ten schools were considered high risk.

Table 1. Proportion of research (2013 to 2015) with human participants by type of researcher

School	Type of Researcher			Proportion of School Researches with Human Participants (%)
	Faculty (%)	Graduate Students (%)	Undergraduate Students (%)	
1	96	57	No data*	61
2	100	86	11	15
3	69	0†	52	58
4	0††	86	100	92
5	80	100	99	98
6	82	100	28	32
7	97	100	90	93
8	0	96	62	76
9	84	90	74	75
10	98	84	90	90
10 Schools	92	73	42	52

* *This kind of research was not stored by the school*
† *Did not offer graduate programs*
†† *No faculty researches were completed between 2013 to 2015*

Table 2. Proportion of research with human participants that are high risk

School	Type of Researcher			High Risk (%)
	Faculty (%)	Graduate Students (%)	Undergraduate Students (%)	
1	1	0.6	No data	0.8
2	0	0	17	12
3	16	No data	0	6
4	0	0.7	4	2
5	0	0	2	1
6	0	0	3	2
7	19	83	19	29
8	0	0	17	8
9	11	4	6	6
10	23	8	4	11
10 Schools	13	9	9	10

DISCUSSION

In summary, there was lack of knowledge among some research directors on the need for research with human participants to undergo ethical clearance and among faculty researchers on the role of the ethics committee in the evaluation of research protocols. Fifty two percent of all research in these schools involved humans as participants and 10% of these were considered high risk.

The first research ethics committees that were set up in the Philippines were based in hospitals to avoid ethics dumping.[17] Ethics dumping refers to bringing a research to a low/middle income country (where ethical review processes, compliance structures and follow-up mechanisms might not be as well-resourced or supported) from a high-income country (where the research would not be permitted or be severely restricted).[18-20]

Being largely hospital-based, the training for its members was usually on Good Clinical Practice focused mainly on clinical trials. The memoranda of the Commission on Higher Education were, therefore, largely "avoided" by the schools because of the "medical" nature of ethics committees and since they only applied to schools with hospital affiliations.

To offset this way of thinking, PHREB did a series of trainings on these schools in a socio-behavioral context to pave the way for the establishment of ethics committee. However, in 2016, ethics committees were not yet created, despite the three memoranda with deadline set by CHED on setting-up and accrediting ethics committees by the end of 2015. This study was then conducted to explore the reasons behind this.

Despite the memoranda:

- Three research directors out of the ten schools in this study only learned about the research ethics committee and its importance in research involving human participants in 2016.
- Only four schools have set up their respective RECs:
  - two were PHREB accredited by 2017 but one of which was said to be "non-functional"
  - two were not accredited

There may be two reasons why memoranda from a government regulating body was not being followed: (1) it may be that these rules were not being disseminated downstream to middle management even though they were posted on the internet for easy access; (2) the timing of the CHED Memoranda in 2015 which coincided with implementation of the K-12 Program.

To bring the Philippines up to par with its neighbors in the ASEAN region and with the world, the Basic Education Act 2013 (Republic Act 10533), commonly referred to as K-12 was signed into law. The K-12 would expand the years of basic education from 10 to 12 years. Senior High School (SHS) would be implemented nationwide beginning with Grade 11 in SY 2016-2017 and Grade 12 in SY 2017-2018[21] decreasing college enrolment in HEIs beginning school year 2016 to 2017 as students would enter senior high school instead of going straight to college and this would be felt over five years until 2020-2021. This had two consequences on HEIs: (1) decreased teaching load of faculty and (2) a significant decrease in the income of both institutions and their employees, including possible loss of jobs for some 25,000 personnel during this period.[22] This made the private higher education sector especially vulnerable to loss of revenue, since they depended almost entirely on tuition for salary of their personnel and operating expenses of the schools.

Since 2013, when the Republic Act 10533 was signed, the concern of all HEIs, especially the private ones, was the viability and sustainability of their institutions. Because the creation of a research ethics committee (REC) requires a substantial amount of money and because the K-12 program will definitely decrease the income of the private schools, the REC creation was deferred despite the memoranda from CHED.

Financial Impact of REC Creation

The joint memorandum order No. 2012-001 dated 28 December 2012 from DOST, DOH, CHED and the UP Manila specifically states that the "institutions must show support to the RECs with the proper funding for office maintenance, administrative staff and honoraria of members."[10] This means that there should be a dedicated budget for the maintenance of an office.

As per interview with research directors, the head of the committee (the chair of the REC) should be a faculty member who must be de-loaded from academic work to only about 3 units of loading. This would essentially make the REC chair almost solely working for the committee for about P50,000 as monthly salary. In addition, salaries for about two offices personnel (about P18,000/month), and office supplies (about P12,000) would be added.

Honoraria of members for appearances in committee meetings and for evaluation of research of faculty, graduate and undergraduate students, which totals about 250 to 1000 theses per year would also be a source of expense for the schools.

The total expenditure would be about P1,000,000 per year, a staggering amount for a research office that allots its budget of P300,000 to P4,000,000 a year just for funding faculty researches and running its own office.

Perceptions on Research Ethics Committees

The research directors and the faculty researchers were one in reporting that most of the research in their schools and the research they do involve human engagement. They both perceived that ethical clearance of a research was needed as a stamp of good quality and a requirement for journal submission.

The questions posted to the research directors were mainly on the perception on the establishment and accreditation of RECs while those of the faculty researchers were their views on the ethical clearance of research.

Discussion with the faculty researchers showed that not all had the full grasp of the research ethics clearance process. It seems that the faculty researchers believed that the research ethics committee is above and superior to any technical review. As such, a research proposal that has obtained a clearance from a REC is considered to have passed "quality control." Moreover, they misconstrued that the members of the committee constantly needed to check for plagiarism in the proposal. Although there is a relationship between research ethics and the recently enacted Philippine Data Privacy Act, (DPA)[23] faculty researchers also believed that the investigator woud be called out if he has breached the DPA law.

All of these showed that the faculty researchers had high regard with the RECs and that its members were viewed to be very meticulous in evaluating research proposals. As such, clearance from an ethics committee was viewed as a measure of near perfection as regards research protocols.

Profile of Research in the Schools

The research directors were asked to estimate the number of researches in their school with human participants and their belief in ethical clearance. These were asked to ascertain if they believed that they have a very high percentage of researches with human participants, and if they believed in the protection of human participants through ethical clearance, and thus, they would support and endorse the creation of an ethics committee in their schools.

The research directors estimated that up to ninety percent (90%) of researches in the schools under this study had human participants. This was not surprising since the organization of schools had very diverse offerings of science and social sciences programs (e.g., accounting, Business Administration, Computer Science, Counselling, Economics, Health and Human Sciences like Biology, History, Education, Hospitality and International Relations, Law, Medicine, Political Science, Psychology, Public Administration, Sociology) with its corresponding mandatory thesis requirements before graduation for both undergra-

duate and graduate degrees. The faculty of these programs also did their own corresponding research.

Majority of all researches of the faculty (92%) and graduate school students (73%) had human participants. On the other hand, the percentage of researches of undergraduate students, which formed the bulk of all research, ranged from 11% to one hundred percent (100%).

Except for two schools, the proportion of researches with human participants was more than 50% for each school. Overall, more than fifty percent (50%) of all the organization's research involved human participants.

The importance of establishing a REC in each of the school cannot be overemphasized.

Proportion of researches with human participation that has high ethical risk

The overall proportion of high-risk researches in the schools was 10%. Except for two schools, with a proportion of high-risk researches of 12% and 29%, all had less than 8% high-risk researches. It should be emphasized that the operational definition of high-risk researches in this study does not in any way conform with the risk as defined by any research ethics board.

The proportion of high-risk researches was culled from this study to give each school a glimpse as to what their REC would be: Level 1 or Level 2, as per PHREB guidelines. The level of accreditation is indicative of both the type of research and the degree of risk involved in the protocols/proposals reviewed by the REC. From the data collected, the schools would protect the participants of their researches with a REC Level 1.

PHREB, the regulator and accreditor of Philippine RECs, grants any of the two levels of accreditation to a REC after an evaluation process. A level 1-accredited REC reviews researches with minimal risk to participants. A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[24] Moreover, a level 1 accreditation is applicable to newly constituted RECs (i.e., less than one year of operations). The researches in this study did not fall in the realm of Level 2 category RECs. A level 2-accredited REC reviews all types of researches except clinical trials required for FDA registration of new drugs. These may entail more than minimal risk to participants. Post-marketing studies may be reviewed by Level 2 RECs.

Methodological Limitations

Although this study tried to capture the views of researchers regarding RECs, the big limitation was the purposive sampling that was done as only faculty researchers who consented and were available at the time of study were interviewed. It would have been more holistic in breadth if all faculty researchers were included.

CONCLUSION

Although the research directors and faculty researchers of the schools in this study were prepared to have their researches evaluated, the task of establishing research ethics committees was daunting. The new K-12 law in the country challenged the very existence of higher educational institutions, especially the private schools, due to the resulting dearth of logistical and financial revenue. Thus, the establishment of an expensive committee was put on hold by the administrators of the schools.

Furthermore, trainings should be conducted on all researchers of the schools to educate them on the exact role of RECs, as they were perceived more as technical reviewers and as enforcers of the country's data privacy law.

Since more than half of the research in the ten schools in this study had human participants, with 10% high ethical risk, it is highly suggested for higher educational institutions in the Philippines to have functioning research ethics committees.

Implications of results

To be an accredited research committee in the Philippines, the Philippines' accreditor (PHREB) requires regular training and remuneration of committee members, a dedicated office and office staff. Not to mention the accreditation fee. These make the creation and maintenance of a REC very expensive. It might be best to start off with a committee committed to the rules and regulations of a PHREB-accredited REC but running within the budget and administrative policy of the HEI.

While most of the faculty of schools in the study have attended trainings in ethics in research and research ethics committees, they have not really imbibed the roles and responsibilities mandated of research committee members. The CHED should look into worthwhile projects to include these roles into the training programs.

This study directs future researchers to explore the different regional policies and practices on the creation of research committees and the logistics in their maintenance. Another agenda would be to investigate surrogate ethics activities that researchers engage in when they do not have the guidance and supervision of a research ethics committee.

Even if the creation of RECs was postponed due to costly maintenance or another reason, the CHED and the school administration should continually strive to offer trainings in research ethics. This is the only way to incorporate ethics in their research activities and in turn, integrate it in their curriculum so that undergraduate and graduate students can also learn and integrate research ethics in their academic activities.

Statement of Authorship

All authors participated in the data collection and analysis and approved the final version submitted.

Author Disclosure

All authors declared no conflicts of interest.

Funding Source

The study was funded by the Department of Science and Technology.

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