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A Desk Review of Standard Operating Procedures of Ethics Committees in the Philippines on the Review of Clinical Trial Protocol Deviations

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Abstract

The review of post-approval submissions such as clinical trial protocol deviations (PDs) is a key function of Ethics Committees (ECs) to ensure data integrity and participant safety. However, the quality of PD management by ECs depends on the SOPs that are anchored in national and international guidelines. This desk review aimed to analyze the SOPs of Level III-accredited ECs in the Philippines in terms of protocol deviation management. From July to September 2025, SOPs of ECs were obtained from institutional websites and through web searches. The SOPs were then compared with recommendations by the Philippine Health Research Board SOP workbook for the presence or absence of the following: (a) policy statement; (b) objectives; (c) scope; and (d) work flow; (e) definition of protocol deviation (PD) or protocol violation (PV); and determine the (f) required timeline for submission to EC; (g) EC processing time; and (h) type of review for the noncompliance. A total of 28 SOPs were reviewed. The results revealed that while most institutional SOPs follow PHREB recommendations, ECs operationalize PD review differently. Key SOP provisions, such as the definition of PD/PV, timelines for reporting, processing time, and the type of review, can affect the quality of EC review and resolution of clinical trial noncompliance. Future research should extend beyond document analysis to investigate the practical implementation of SOP provisions regarding protocol deviation management.

Keywords: *Clinical Trial, Ethics Committees, Philippines, Protocol Deviation, Standard Operating Procedures.*

Introduction

A protocol deviation (PD) is any alteration, variation, or departure from the study design or procedures outlined in the approved protocol [1-3]. Protocol deviations are frequently observed in clinical trials and can substantially affect the quality and integrity of the study data. Noncompliance with the approved protocol can come from the research participants, the sponsor, or the investigational team [4, 5].

Protocol deviations are usually classified as minor or major depending on their possible impact on patient safety, research integrity, and data quality [4]. While minor deviations usually concern administrative or procedural concerns that are less significant, major deviations are commonly described as those that can compromise the scientific integrity of the data or threaten the safety of the participants. The terms “non-important” and “important” protocol deviations are used interchangeably for departure from the protocol that is considered minor or major respectively [5]. In addition, important protocol deviations are sometimes used interchangeably with protocol violations, which, as per International Council for Harmonisation (ICH) E3 annex IV a refers

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to deviations that result in the withdrawal of a subject from trial participation whether this is incurred by the investigator or the subject [2].

Maintaining regulatory compliance, guaranteeing data integrity, and preserving participant safety all depend on accurately reporting protocol deviations. Regulatory bodies including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) require sponsors and researchers to document and disclose deviations depending on their severity. The US Food and Drug Administration and the European Medicines Agency (EMA) mandate that sponsors of clinical trials report "serious" or "persistent" deviations impacting participant welfare or data integrity [6, 7]. On the other hand, ICH-Good Clinical Practice (GCP) E6 and the WHO GCP handbook clearly define the responsibilities of sponsors, investigators, and ethics committees (ECs) in handling protocol deviations. The sponsor is responsible for determining the trial-specific criteria for important deviations, and appropriate actions, including risk management and reporting to the ethics committee and/or regulatory authority. The investigator on the other hand is responsible for documenting all protocol deviations incurred at the clinical trial site and communicating them to the sponsor. Protocol deviations classified as "important" should be investigated and explained, and when warranted, a corrective action and preventive action (CAPA) should be implemented to prevent their recurrence. The investigator is expected to notify the sponsor, the ethics committee, and/or the regulatory authorities promptly, especially for deviations that are committed to eliminate any imminent danger to study participants. The responsibility for the review and approval of the protocol deviations submitted by the sponsor or investigator lies with the ethics committees [1, 8].

Institutionalization of formal ethics review processes commenced in the Philippines throughout the late 20th century. Established in 1987 under the Department of Science and Technology (DOST), the Philippine Council for Health Research and Development (PCHRD) aims to advance ethical health research. One of its goals was to establish research ethics committees (RECs) nationwide [9]. The Philippine Health Research Ethics Board (PHREB) was officially founded in 2006 under the Philippine Council for Health Research and Development (PCHRD), a Department of Science and Technology (DOST) agency, with assistance from the Department of Health (DOH) and the University of the Philippines Manila. The establishment was prompted by a series of consultative workshops with ethicists, researchers, and politicians, who acknowledged the necessity to align local practices with worldwide standards such as ICH GCP and to solve ethical gaps identified by multinational trials (e.g., early HIV studies). PHREB's role encompassed the formulation of national ethical principles, the accreditation of Ethics Committees, and the promotion of capacity-building, as formalized in the National Ethical principles for Health Research published in 2006. The rules outlined seven ethical principles—scientific validity, equitable subject selection, risk-benefit analysis, informed consent, independent review, respect for participants, and social value—establishing a framework for ethics committee operations countrywide [10].

As of 2025, there are 97 PHREB accredited ECs in the Philippines, 45 are Level III, 30 are level II, and 22 are level I. Of the 45 level 3-accredited ECs, majority are concentrated in the National Capital Region (NCR), and others are from Region I, III, IV, V, VI, VII, IX, and XI [11]. PHREB Level III accreditation represents the highest level of recognition awarded to Research Ethics Committees (RECs) in the Philippines, allowing them to evaluate all categories of research, encompassing clinical trials (Phases 1–4) and studies necessary for Food and Drug Administration (FDA) registration.

Although these national guidelines establish a cohesive policy framework, individual RECs possess flexibility to develop their internal SOPs to accommodate institutional contexts. This versatility may lead to inconsistencies in the definitions, classifications, reporting timelines, and review processes for protocol deviations. To date, no studies were done to evaluate how RECs in the Philippines align with the PHREB in terms of protocol deviation review and management.

This desk review aim to analyze the Standard Operating Procedures (SOPs) of PHREB-accredited Research Ethics Committees (RECs) in the Philippines, concentrating on the management of protocol noncompliance reports. The findings are anticipated to guide the future standardization of REC processes and enhance ethical supervision systems within the country.

Materials and Methods

This study utilized a desk review methodology, conducting a documentary analysis of publicly accessible Standard Operating Procedures (SOPs) from PHREB-accredited Research Ethics Committees (RECs) in the Philippines involved in the review of clinical trials.

From July to September 2025, a thorough search was conducted on the websites and institutional portals of all PHREB-registered Research Ethics Committees (RECs). Search criteria encompassed "Standard Operating Procedures," "SOP manual," "ethics committee," and "protocol deviations." Further inquiries were conducted on the PHREB, and institutional or university ethics committee websites. SOPs were obtained in PDF or Word format, and the institutional name, and version date, were documented. Cross-referencing was conducted using PHREB's official registry of accredited RECs.

Criteria for Eligibility

Documents were included if they:

1. Are Standard Operating Procedures of a Level III PHREB-accredited Research Ethics Committees.
2. Include protocol non-compliance report management.
3. Had identifiable version or revision dates.

Documents were excluded if they:

1. Are not accessible (e.g., institutional log-in credentials are needed).
2. Not finalized (i.e., no effective date).

Data Extraction and Analysis

A structured data extraction form was created to capture the SOP version, effectivity date, the SOP’s policy statement, objective, scope, workflow, PD and PV definition, timelines for submission of non-compliance report, processing timeline, and type of review. The PHREB SOP workbook [12] is used as comparison for the SOP elements analyzed in this review. To maintain the confidentiality of the ECs, their names were replaced with code numbers.

Results

As of August 2025, the PHREB listed a total of 44 Level III-accredited RECs. Of them, 29 (about 65%) had publicly accessible Standard Operating Procedures posted on institutional websites. Following the screening process, 28 Standard Operating Procedures (SOPs) satisfied the inclusion criteria, with specific sections on the management or evaluation of protocol non-compliance (Fig 1).

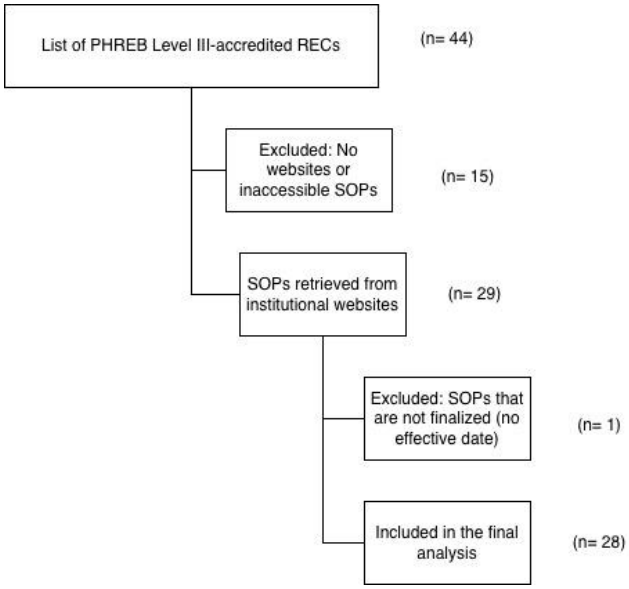

Figure. 1. PRISMA-Like Flow Chart for SOP Selection

The summary of the twenty-eight SOPs on the review of protocol deviation is summarized Table 1. The ECs included in the desk review are from the Cordillera Autonomous Region (1); National Capital Region (18); Bicol Region (1); Central Visayas (3); Eastern Visayas (1); Western Visayas (1); and Davao Region (3). The SOP versions ranges from 1-12 and their effectivity dates ranges from 2017 to 2024.

The Philippine Research Health Research Ethics Board (PHREB) SOP Workbook [12] was used as a reference for comparing the process of each EC's SOP in terms protocol deviation and violation report management. Table 2 presents the items that are present or absent in the ethics committees' SOPs. The PHREB prescribed the PD SOP format, containing a policy statement, objective of the activity, scope, workflow, and terms to be defined for effective SOP implementation. The workflow contains 7 steps: Step 1 - Receipt and documentation of report of protocol violations and deviations in the logbook/database; Step 2 - Retrieval of pertinent protocol file; Step 3 - Notification of Chair and primary reviewers; Step 4 - Determination of type of review; Step 5 - Inclusion of report in the agenda of the next REC regular meeting; Step 6 - Communication of Decision to the Principal Investigator/researcher; and Step 7 - Filing of all related documents and update of the protocol database.

Majority (22) of the ECs have a policy statement, except for 6 ECs (7, 22, 30, 38, 39,42). Of those having a policy statement, compliance with ICH-GCP and the National Ethical Guidelines were adhered to. However, almost all of the ECs did not specified whether the policy covers investigator-initiated studies (or non-clinical trials) or industry-sponsored trials, except for 2 ECs (10, 35).

Twenty-five ECs have included an objective or purpose section in their SOPs. The common statement is that the SOP's objective is to describe the PD review process and its commitment to protecting the research participant's rights, safety, and well-being, and ensuring data credibility and integrity.

Only 1 EC (43) did not included a scope section. For the 27 ECs that have a scope, the statements include: (a) it applies to previously-approved studies; and (b) the beginning and the end of the process that applies to those who submit the report and those that are involved in the PD management. In addition, 11 ECs (6, 7, 8, 13, 16, 27, 29, 30, 37, 40, 44) have included that the scope of reporting of PDs also include (a) failure to comply with national or international guidelines and (b) failure to respond to IRB reporting timelines or requests.

As for the workflow, 6 ECs (1, 8, 12, 20, 33, 44) have SOPs aligned with the PHREB's 7 steps. Twenty-two ECs (6, 7, 12, 15, 16, 17, 21, 25, 26, 27, 29, 30, 31, 34, 35, 37, 38, 39, 40, 42, 43, 44) have 6 steps, omitting step 2 (retrieval of protocol file). A total of 7 ECs (13, 15, 34, 37, 39, 43, 44) have 5 steps that omitted step 3 in addition to other steps. Only 4 ECs (6, 16, 27, 34) did not include step 4 in their workflow and 1 EC (37) did not include step 5 in their workflow. All 27 ECs have included step 5 in their workflow and only 3 ECs (22, 25, 28) did not have step 6.

There are 3 ECs that have more than 7 steps in their workflow. EC #10 added a step of discussing the major PD or PVs. EC #37 also have an extra step after filing of documents, which is follow-up on the PDs that ECs recommended further action. EC #40 has 10 steps- the 3 extra steps are: (1) PI submission of the report; (2) Review of the primary reviewer; and (3) Review of the EC chair on the recommendation of the primary reviewer.

Table 1. Summary of Identified EC SOPs on the Review of Protocol Deviations

EC Code	Region	SOP Version	Effective Date
33	National Capital Region (NCR)	1	2023
1	Cordillera Autonomous Region (CAR)	5	2022
6	Bicol (V)	5	2023
34	National Capital Region (NCR)	4	2018
8	Central Visayas (VII)	3	2023
29	National Capital Region (NCR)	6	2020
16	Davao (XI)	5	2023
25	National Capital Region (NCR)	1	2021
27	National Capital Region (NCR)	6	2023
13	Eastern Visayas (VIII)	7	2023
43	National Capital Region (NCR)	4	2022
10	Central Visayas (VII)	5	2023
44	National Capital Region (NCR)	5	2022
37	National Capital Region (NCR)	6	2020
15	Davao (XI)	6	2024
40	National Capital Region (NCR)	5	2022
12	Central Visayas (VII)	6	2018
26	National Capital Region (NCR)	4	2021
30	National Capital Region (NCR)	12	2024
35	National Capital Region (NCR)	6	2023
17	Davao (XI)	2	2017
38	National Capital Region (NCR)	2	2024
22	National Capital Region (NCR)	6	2022
31	National Capital Region (NCR)	6	2022
20	National Capital Region (NCR)	5	2022
39	National Capital Region (NCR)	6	2023
42	National Capital Region (NCR)	7	2022
7	Western Visayas (VI)	3	2021

Table 2. Comparison of Level III EC SOPs Contents vs. PHREB SOP Workbook on PD/PV Report Management

				Workflow						
EC Code	**Policy Statement**	**Objective**	**Scope**	**Receipt & documentation**	**Retrieval of protocol file**	**Chair/ reviewer Notification**	**Determination of type of review**	**Inclusion in regular meeting**	**Communication of decision**	**Filing**
33	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
1	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
6	☑	☑	☑	☑	☒	☑	☒	☑	☑	☑
34	☑	☑	☑	☑	☒	☒	☒	☑	☑	☑
8	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
29	☑	☑	☑	☑	☒	☑	☑	☑	☑	☑
16	☑	☒	☑	☑	☒	☑	☒	☑	☑	☑
25	☑	☒	☑	☑	☒	☑	☑	☑	☑	☒
27	☑	☑	☑	☑	☒	☑	☒	☑	☑	☑
13	☑	☑	☑	☑	☑	☒	☑	☑	☑	☑
43	☑	☒	☒	☑	☒	☒	☑	☑	☑	☑
10	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
44	☑	☑	☑	☑	☒	☒	☑	☑	☑	☑
37	☑	☑	☑	☑	☒	☒	☑	☒	☑	☑
15	☑	☑	☑	☑	☒	☒	☑	☑	☑	☑
40	☑	☑	☑	☑	☒	☑	☑	☑	☑	☑
12	☑	☑	☑	☒	☒	☑	☑	☑	☑	☑
26	☑	☑	☑	☑	☒	☑	☑	☑	☑	☑

30	☒	☑	☑	☑	☒	☑	☑	☑	☑	☑
35	☑	☑	☑	☑	☒	☑	☑	☑	☑	☑
17	☑	☑	☑	☑	☒	☑	☑	☑	☑	☑
38	☒	☑	☑	☑	☒	☑	☑	☑	☑	☒
22	☒	☑	☑	☑	☒	☑	☑	☑	☑	☒
31	☑	☑	☑	☑	☒	☑	☑	☑	☑	☑
20	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
39	☒	☑	☑	☑	☒	☒	☑	☑	☑	☑
42	☒	☑	☑	☑	☒	☑	☑	☑	☑	☑
7	☒	☑	☑	☑	☒	☑	☑	☑	☑	☑

The PHREB defines protocol deviation as non-compliance that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety, and well-being or integrity of data. Conversely, a protocol violation increases the risk or decreases the benefit to participants that consequently impact participants' rights, safety, and well-being or integrity of data [12]. Although there is no prescribed timeline for submission and processing of non-compliance reports as well as for type of review depending on the classification of non-compliance, the reviewed SOPs revealed varying turnaround time for submission, processing and type of EC review. These are summarized in Table 3.

Table 3. Comparison of Non-Compliance Definition, Prescribed Timeline for Submission, Processing Time, and Type of EC Review

EC Code	Adapted PD Definition?	Adapted PV Definition?	Timeline for submitting non-compliance report	EC Processing of reports (working days)	Non-compliance discussed at full board meeting?
33	☒	☒	7 calendar days from detection	NS	Both minor and major PD
1	☑	☑	Within a week of the event	30	Major PD/PV only
6	☒	☒	NS	14	Major PD/PV only
34	ND	ND	NS	NS	Only when raised by PR
8	ND	ND	Within a week of the event	14-16	Major PD only
29	☒	☒	NS	NS	Major PD/PV only
16	☑	☑	NS	NS	PV only
25	☒	☒	NS	NS	Major PD/PV only
27	☒	☒	NS	14	PV only
13	☒	☒	Within a week of the event	NS	Major PD only
43	☒	☒	At the soonest time	NS	Major PD only
10	☒	☒	Within a week from detection	21	Major PD only
44	☒	☒	At the soonest time up to 6 months after the event	14	Major PD only
37	ND	ND	Within 2 months upon recognition of the PI	NS	Both PD and PV
15	☒	☒	At the soonest time, within a month from event detection	42	Both PD and PV
40	☒	☒	7-14 days from detection	19-30	Both PD and PV
12	☑	☑	NS	NS	PV only
26	☒	☒	Within 14 days of awareness	NS	Major PD/PV only
30	☒	☒	NS	14	Both minor PD and major PV

35	☑	☑	Within 5 days of awareness (PD) Within 10 days of awareness (PV)	12-28	Both PD and PV
17	☑	☑	NS	NS	Both PD and PV
38	☒	☒	NS	NS	Both minor and major violation
22	☑	☑	NS	NS	PV only
31	☑	☑	Within 1 week from detection	NS	Major PD only
20	☑	☑	Within 1 week from detection	NS	Major PD only
39	ND	ND	At the soonest time up to 6 months after the event	NS	All non-compliance
42	☒	☒	At the soonest time up to 6 months after the event; Within 48 hours if PD resulted in SAE	NS	All non-compliance
7	☒	☒	NS	14	PV only

Legend: ND- Not defined; NS- Not specified; PD- Protocol deviation; PV- Protocol violation; SAE- Serious Adverse Events.

Out of 27 ECs, only 8 (1, 12, 16, 17, 20, 22, 31, 35) adapted the PHREB definition of protocol deviation and protocol violation. Sixteen ECs (6, 7, 10, 13, 15, 27, 26, 29, 30, 25, 33, 38, 40, 42, 43, 44) defined "minor protocol deviation" as the equivalent of protocol deviation, and "major protocol deviation" as the equivalent of protocol violation. Four ECs (8, 34, 37, 39) did not define protocol deviation or violation in their SOP.

The ECs have varying timelines for the submission of protocol non-compliance reports from investigators. EC #43 recommended reporting variances at the soonest time. Seven ECs (1, 8, 33, 10, 13, 20, 31) prescribed submitting within 1 week from the detection of the non-compliance, while 2 ECs (26, 40) requires 14 days from the recognition of PDs. EC #35 specified submission of PDs within 5 days of awareness, and within 10 days of awareness for PVs. Other ECs have broader timelines- EC #15 specified reporting PDs at the soonest time up to a month from event detection, while EC #44, #39, and #42 allows up to 6 months. EC #42 added a 48-hour timeline for submission of PD if it resulted to an SAE. Twelve ECs (6, 7, 12, 16, 17, 22, 25, 27, 29, 30, 34, 38) did not specified a timeline in their SOP.

The turnaround time for processing the reports from receiving until filing of documents varies from one EC to another. These ranges from 12-42 working days. Seventeen out of 28 ECs (12, 13, 16, 17, 20, 22, 25, 26, 29, 31, 33, 34, 37, 38, 39, 42, 43) did not specified their processing time.

In the determination of type of review, while PHREB did not strictly stated which type is applied to a particular non-compliance, the ECs have varying decision when it comes to identifying which NC will undergo full board discussion or expedited review. Ten ECs (15, 17, 30, 33, 35, 37, 38, 39, 40, 42) applied full-board review regardless of the type of non-compliance (minor/major or deviation/violation). Seventeen ECs (1, 6, 7, 8,

10, 12, 13, 16, 20, 22, 25, 26, 27, 29, 31, 43, 44) stated in their SOP that only “major PDs” or “protocol violations” will be discussed during full board meeting, while EC #34 indicated that the NC will only be discussed during full board meeting only when raised by the primary reviewer.

Discussion

This desk review examined Philippine Research Ethics Committees (RECs) publicly available Standard Operating Procedures (SOPs) for reviewing clinical trial protocol deviations and their consistency with the PHREB SOP Workbook. The data show that while most institutional SOPs follow PHREB recommendations, RECs operationalize protocol deviation review differently. The PHREB SOP Workbook requires RECs to have clear, written protocols for continuous review, including protocol deviations and non-compliance receipt, assessment, and documentation. This study found that all SOPs required investigators to report protocol noncompliance and RECs to process these submissions in accordance with regulatory requirements, thus meeting PHREB's recommendations.

However, alignment was often incomplete. The PHREB SOP Workbook contains model language and examples for handling deviations, although many institutional SOPs did not adopt them. Only several SOPs clearly differentiated minor and major protocol deviations or indicated escalation procedures (e.g., chair-level review versus full-board review). The REC may struggle to apply consistent, risk-proportionate oversight, a principle implied in PHREB guidance on continuing review.

To the knowledge of the researcher, there are no studies done locally that systematically analyze REC SOPs on protocol deviation management, but this desk review confirms PHREB regional assessments and capacity-building workshops that found SOP content and procedural clarity vary across institutions [13-15].

The differences in the required time for reporting and the time it takes to process the PD reports affect to how site issues especially those that impact data quality and participant safety are resolved. If the noncompliance report is major, and this is only reported after a month or in the case of some ECs, until 6 months after the event, while the EC will take a month on average to process the submission, this would mean a missed opportunity to promptly act on a deviation. In addition, if this affected several trial participants, the noncompliance is perpetuated until the PI or the monitor becomes aware of it thus delaying appropriate actions resolve and prevent future PD occurrence. While it is impossible for ECs to proactively detect PDs, it is expected that PIs report protocol noncompliance to ECs as per national [16, 17] and international guidelines [1, 7].

There are no local studies that focused on EC processing of PD reports, but the findings of Halwai and Vaswani on Indian ECs suggest that PD management is challenging because PIs do not report PDs or they do not accept PDs, and that there is no clear SOP [18]. In clinical trials or any other research, reducing protocol noncompliance and their impact is important, and this necessitates joint efforts of the PIs and ECs to establish clear guidelines for reporting and managing PDs [19]. Furthermore, in the process of protocol management by ECs, resolving and filing PD reports should not be the final steps. In this study, no local ECs have mentioned in their SOP regarding regular reviews on the reports of protocol noncompliance, including the effectiveness of CAPAs unlike in other ECs abroad. This is an important addition EC SOPs to improve the quality of reviews as well as to serve as basis for training for both EC members and investigators in light of ensuring high quality conduct of clinical trials [19-21].

This strength of the study lies in its systematic desk evaluation of publicly available

Standard Operating Procedures (SOPs) from PHREB-accredited Research Ethics Committees, which objectively evaluates protocol deviation review formal procedural advice. Anchoring the analysis on the PHREB SOP Workbook improves its relevance to national ethical governance and EC accreditation. However, the study is constrained by its dependence on publicly available documents, which may not reflect internal revisions or supplementary procedures. Furthermore, the study did not investigate actual SOP implementation to give further meaning to the analysis of SOPs.

Conclusion

Ethics Committees play a vital role in promoting clinical trial data integrity and participant safety not only through reviewing initial submissions but also on post-approval submissions such as protocol noncompliance reports. Standard Operating Procedures on PD management guide ECs in providing timely, consistent, and appropriate recommendations to site PIs. Inconsistencies or partial alignment of SOPs across PHREB accredited level III ECs in the country with the PHREB SOP workbook such as workflow, definitions of PD/PV, required timelines for reporting, including turnaround time for processing, and type of review can affect the overall quality of review and resolution of noncompliance at trial sites.

Future research should extend beyond document analysis to investigate the practical implementation of SOP provisions regarding protocol deviation management. Mixed-method techniques that integrate REC interviews, meeting minutes, and case reviews may yield deeper understanding of the EC processes and the consistency of their application. Analysis of PHREB accreditation results with emphasis on PD management can also shed light regarding SOP implementation, including the challenges that ECs encounter in ensuring quality reviews and efficient process. This research can enhance current findings and bolster evidence-based improvements in national guidelines, especially in terms EC accreditation and REC capacity-building efforts.

Conflict of Interest

Nil.

Ethical Approval

This research was submitted to the University of the Philippines Manila Research Ethics Board and was granted ethical clearance (UPMREB 2025-0500-EX) prior to its implementation.

Data Availability

The SOPs analyzed in this study are publicly available in the websites of the Ethics Committees, with some available via web search. The names of the ECs were intentionally coded to protect the identity of the ECs, but the list of Level III-accredited ECs can be found in the PHREB Website (https://ethics-accreditation.healthresearch.ph/accredited-rec/3/4) and the compiled data set are available upon reasonable request from the author.

Author Contributions

The author is responsible for the conceptualization and implementation of the research, up to the writing of the publication manuscript.

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