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The Role of Ethics Committees and Regulatory Requirements in Shaping Health Research in the Philippines: A Qualitative Investigation

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Abstract

In recent decades, the role of ethics in health research has gained global recognition. However, institutional review boards (IRBs) are sometimes seen as obstacles rather than enablers of research. This study focuses on the Philippines, a country where the dynamics of health research ethics and IRBs remain underexplored, offering insights applicable to other low- and middle-income settings. Between July and October 2020, semi-structured interviews were conducted with Filipino health researchers to understand their experiences with IRBs and the ethics approval process. Insights were also gathered from individuals who have worked directly within IRBs.

Across clinical, public health, and social science domains, ethics review emerged as an issue of access and inequality. Researchers outside established institutions, those in regions without accredited IRBs, independent investigators, and those with limited funding or highly specialized topics—especially non-clinical researchers—face disproportionate hurdles. As a result, the research ecosystem tends to favor well-funded investigators and studies that are more likely to attract financial support. Improving fairness in health research requires systemic changes, but immediate steps could enhance equity in the ethics review process. Recommendations include stronger institutional oversight, regulation of IRB fees, and creating a more supportive environment for early-career, student, independent, and non-clinical researchers. The study also reflects on the implications of these findings for the broader research culture.

Keywords: Ethics committees, Regulatory requirements, IRB, Health research

Introduction

Ethical oversight in human research has become increasingly central in recent decades. To safeguard participants and ensure ethical conduct, academic and professional institutions worldwide have implemented guidelines and established ethics review boards, commonly known as IRBs. Securing approval from these boards is now a prerequisite for starting, funding, and publishing research in health-related fields.

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Despite their necessity, IRBs are often perceived as cumbersome. Studies have highlighted the time and financial burden of ethics review, particularly for multi-site studies [1], and the challenges faced by qualitative and social justice–oriented research under a biomedical-centric ethics framework [2]. Complaints frequently focus on excessive paperwork, inconsistent decisions across boards, and inadequate evaluation of certain research types [3]. Notably, there is no standardized benchmark for evaluating ethics review systems, and in the Philippine context, little research has examined these processes [3].

Guided by these observations, this study asks: (1) how ethical regulations shape health research in the Philippines, (2) what challenges Filipino researchers encounter with IRBs, and (3) how perceptions differ across research disciplines. Using qualitative interviews

with both researchers and IRB personnel, the study maps barriers and facilitators in the ethics approval process and provides policy suggestions relevant for other low- and middle-income countries.

Ethics review in the Philippines

Compared to countries in the Global North, formal ethics oversight developed relatively late in the Philippines. While IRBs were widespread in the U.S. by the late 1980s [4] and in Portugal by 2000 [5], the Philippines was only beginning to establish a National Ethics Committee aimed at promoting ethics review [6]. At that time, only the Research Institute for Tropical Medicine had its own IRB [7], and by the early 2000s, just half of Philippine institutions had IRBs [8].

The Philippine Health Research Ethics Board (PHREB), established in 2006, oversees IRB accreditation and performance, and coordinates with local and international partners [9]. As of 2021, 104 IRBs are accredited, with a significant concentration in Metro Manila. Major universities created IRBs in the last 15 years: University of the Philippines Manila in 2010 [10] and Ateneo de Manila University in 2015 [11]. Social sciences research gained dedicated oversight when the Philippine Social Science Council formed its own IRB in 2017 [12].

To simplify multi-site approvals, the Department of Health established the Single Joint Research Ethics Board (SJREB) in 2017. This board provides blanket approval for studies across all DOH-affiliated hospitals, eliminating the need for separate site-specific approvals [13].

Materials and Methods

Between July and October 2020, we carried out semi-structured interviews with 40 researchers across the Philippines. Due to the COVID-19 pandemic, all interactions were conducted remotely, with our research team members—each experienced in qualitative methods—located in different regions of the country. Following Mays and Pope's [14] recommendations for purposive, theoretically guided sampling, and drawing on Marshall's concept of researchers' "practical knowledge of the research area" [15], participants were intentionally recruited through peer referrals and targeted searches via Google Scholar. Recruitment prioritized inclusivity, encompassing individuals involved in the ethics review process, including researchers, IRB members, journal editors, government health officials, and hospital residency training officers.

Adjustments for the pandemic required pragmatic adaptations. Given the widespread disruptions to academia and research culture, initial outreach focused on participants already known to the research team—via phone, text, or email—before extending invitations to unfamiliar contacts. Prior to each interview, participants received the interview guides, which allowed them to review the questions in advance and raise any concerns regarding their participation.

Participants were initially classified into three primary disciplines: clinical research, public health research, and social science research. A fourth category comprised IRB members, while key informants—such as journal editors, heads of private research organizations, and current or former government officials in health and research sectors—formed a fifth category. Many participants belonged to multiple categories, so the summed counts by discipline exceed the total number of participants. Geographic distribution was predominantly Metro Manila, with only three exceptions: two participants from Northern Mindanao and one from Cavite. Nearly half were affiliated with the University of the Philippines system. Of the 40 participants, 15 were early-career researchers, including graduate students, while the remainder were established researchers.

The final sample size was determined based on data saturation. During data collection, the team routinely reviewed interview findings to assess whether sufficient saturation had been achieved within each participant category. Although the study aimed to provide a preliminary rather than exhaustive picture, saturation was generally reached after approximately 10 interviews per category, after which further recruitment for that category was halted. Participant selection also considered gender balance, institutional affiliation, and research discipline, summarized in **Table 1**.

Table 1. Description of participant characteristics

Characteristic	Category	Number of Participants
Gender	Male	21
	Female	19
Research Discipline	Clinical research	13
	Public health research	11
	Social science research	14
	IRB membership	10

	Key informant	5
Institutional Affiliation	University of the Philippines system	17
	Private universities or teaching hospitals	10
	Private research organizations	9
	Other affiliations	4

Interviews were conducted remotely via phone or video-conferencing platforms such as Zoom, with the ability to join online being the only exclusion criterion. Each session lasted approximately 30–45 minutes. While the interviews generally followed a structured format—starting with participants' personal backgrounds, including professional experience and engagement with IRBs, and then moving to broader topics like perspectives on ethical research, IRB practices, and their influence on research culture—questions were adapted according to the participant's role, resulting in four separate interview guides.

To minimize interviewer bias, team members, all experienced in qualitative research and familiar with IRBs, adhered closely to the guide, asking one open-ended question at a time and maintaining their role strictly as facilitators rather than co-interpreters of the participants' responses. Early interviews functioned as pilot tests, and subsequent sessions incorporated minor adjustments to reduce any inadvertent bias while allowing participants' answers to inform follow-up questions.

Electronic consent forms were signed prior to participation, and tokens of appreciation were delivered online. Audio recordings were transcribed by personnel bound by nondisclosure agreements. The research team anonymized transcripts by removing identifying information, and all 40 transcripts were securely stored in a password-protected folder accessible only to the research team.

Data were uploaded to an offline NVivo 10.0 database and analyzed using deductive thematic analysis. Guided by the literature review, each researcher independently coded the transcripts to generate initial codes, with frequent team consultations to reduce potential bias. Comparison of codes led to preliminary themes, followed by a second round of review to finalize themes through consensus. The study received ethics approval from the UP Manila Research Ethics Board (UPMREB 2019–259-01).

Results and Discussion

Researchers across clinical, public health, and social science domains uniformly recognized the significance of ethics in their work. Clinical researchers, for instance, emphasized that IRB oversight makes conducting trials safer than before. However, procedural strictness has also drawn criticism; one participant described the ethics application process as "intimidating." Below, we outline these concerns, including insights from researchers who are also IRB members, highlighting differences across disciplines.

Lengthy ethics review process

A recurrent and prominent concern was the protracted timeline of ethics reviews in the Philippines. Participants reported that initial decisions from IRBs typically take two weeks to a month, while final approvals often require two to three months. When accounting for revisions and resubmissions, the entire process can extend to nearly a year, causing substantial delays even when researchers anticipate lengthy review periods. One public health researcher recounted a project delayed for almost a year despite reviewers requesting no revisions. Similarly, a consultant from a tertiary hospital noted:

"Our hospital was supposed to participate in an international clinical trial, but ethics approval took so long that the trial was nearly over by the time we received it, forcing us to withdraw."

Such delays are especially problematic for time-sensitive studies or projects with strict deadlines. A private research firm head cited at least three recent cases where potential international collaborators withdrew from Philippine-based studies due to extended approval timelines. Even students experienced setbacks, with thesis projects delayed or abandoned because of slow IRB responses. Consequently, researchers often have to incorporate anticipated review durations into study planning or forego aspects of their projects that cannot accommodate delays.

Within the Philippine research community, some IRBs have developed reputations for processing applications more quickly. Participants identified certain boards, including those in private hospitals, as "machine-like" in their predictable and rapid approvals, making them preferred choices for researchers working under tight schedules despite being less prestigious than university-based boards.

Some participants reported positive experiences with IRBs capable of delivering initial responses within two weeks and completing approvals within a month. The COVID-19 pandemic also prompted some boards to improve efficiency, such as accepting email submissions. Nevertheless, the prevailing sentiment among researchers was that IRBs generally do not process applications as promptly as needed, and more manageable timelines are required to support timely research.

Costs of ethics review

Regarding financial considerations, most participants indicated that IRB fees are manageable when a study has secured funding. However, our interviews revealed wide disparities in charges across boards. Some university-based IRBs waive fees for faculty and students, while others offer partial discounts. On average, application fees ranged from PHP 20,000–50,000 (US$ 416–1,040), with some reaching as high as PHP 80,000 (US$ 1,664). Even for funded projects, participants noted that these costs can consume a significant portion of the research budget. For independent and student researchers, the impact is particularly burdensome, as fees must often come from personal resources. One public health researcher suggested that this financial barrier may restrict research opportunities to well-funded circles, such as established academic institutions, while discouraging newcomers or independent investigators:

"As head of [redacted private research firm], even a PHP 30,000 [US$ 624] fee feels steep. International PhD students attempting research in the Philippines are often shocked at how much some ethics boards charge."

The lack of standardization in IRB fees raised additional concerns. Some participants felt that certain boards exploit the absence of regulation. One participant explained:

"Ethics review invoices often include two components: a basic review fee, typically around PHP 20,000 [US$ 416], and an institutional fee, which can be highly arbitrary. In one project with an American agency, a hospital demanded nearly PHP 100,000 [US$ 2,081] with no justification, clearly assuming we could pay. It's ironic that ethics boards engage in such practices."

Such unpredictability has led some to view ethics review as increasingly commercialized. A social scientist remarked:

"There seems to be a market for ethics review. Reviewers read protocols, provide feedback, and approve them, yet boards can earn PHP 50,000 [US$ 1,040] in as little as a month. It's potentially lucrative."

This sentiment was echoed by a member of a private hospital IRB, who acknowledged that while forming an in-house IRB positions hospitals as research leaders, it also represents a substantial source of revenue, particularly from multi-country clinical trials.

Geographical concentration of ethics committees

Beyond financial and procedural challenges, participants noted that most IRBs are located in Metro Manila, posing difficulties for researchers in other regions. A clinical researcher from Northern Mindanao shared that the local hospital board was essentially the only option for ethics approval. Similarly, a social science researcher from a neighboring town noted that he routinely had to travel out of town to secure approval.

While the Single Joint Research Ethics Board (SJREB) has helped streamline approval for multi-site studies, it has limitations. One Department of Health official noted early resistance from individual IRBs, concerned about losing autonomy and fee revenue. Additionally, the SJREB's blanket approval applies only to DOH-affiliated hospitals; private institutions may still require separate submissions. A public health researcher described how a single study ended up requiring approval from three different boards—one SJREB and two private IRBs—demonstrating that, for researchers outside major urban centers or institutions without their own IRBs, securing ethics approval remains a significant initial hurdle.

Ethics review geared toward clinical research

Non-clinical researchers consistently voiced a concern not typically shared by their clinical peers: that IRB procedures are predominantly tailored to clinical studies, making them ill-suited for non-clinical disciplines. This clinical focus is evident in the forms and documentation that IRBs require. As one public health researcher explained:

"It's already burdensome to deal with extensive paperwork, especially from boards that haven't transitioned to digital formats. Many of the questions are irrelevant to non-clinical research. It would be much more efficient if templates were designed according to specific study types."

This clinical bias extends to the composition of IRBs and the expertise—or lack thereof—members bring. A social scientist observed that hospital-based IRBs, primarily

composed of clinicians, are often ill-equipped to assess social science research competently. Beyond representation, boards often lack interdisciplinary training, limiting their capacity to fairly evaluate non-clinical studies.

A clinician conducting mostly qualitative research highlighted the consequences of this mismatch:

"Boards may reject or question protocols not because they are ethically flawed, but because of subjective concerns about methodology, stemming from unfamiliarity with the methods themselves."

Similarly, a participant from a firm that assists with hospital-based protocol processing noted that IRBs frequently adopt a reactive stance:

"They respond only to what researchers present rather than knowing the right questions to ask. I've seen numerous studies using novel data-collection methods being heavily scrutinized simply because the tools were unfamiliar."

Such experiences help explain complaints about IRBs overstepping their authority or "interfering with studies." Even when boards justify their actions by claiming that ethical soundness requires methodological or technical rigor, researchers—particularly those in non-clinical fields—often remain unconvinced. Across clinical, public health, and social science sectors, participants identified this tendency to exceed mandates as a major source of tension, which intensifies the further a study diverges from clinical research.

Several social scientists recounted instances where IRBs insisted on written informed consent for vulnerable populations in studies where non-written consent is considered safer practice, sometimes forcing researchers to abandon their projects. In ethnographic research with indigenous communities—where participants are recognized as co-generators and co-owners of data—researchers struggled to convince boards that standard biomedical practices, such as mandated data destruction, were not applicable. One university professor shared an experience with an IRB objecting to a thesis proposal on methodological grounds rather than ethical concerns:

"It was an online survey with no sensitive content—I had already vetted it. After repeated back-and-forth with the board, I had to firmly insist that they stop interfering with the methodology. Eventually, they allowed the study to proceed as originally designed."

Ethics review for the sake of approval?

The issues outlined above collectively shape how Filipino researchers perceive and navigate the ethics approval process, influencing choices about research topics, which IRBs to approach, and even whether to pursue certain projects. One social scientist admitted:

"It can be very discouraging to conduct research here, because you go into it assuming you'll have to fight just to get approval. I've abandoned projects simply because I doubted they would pass review."

Given the relative infancy of the ethics review system, the same participant observed:

"It often feels like these boards treat every submission as if it were a dissertation defense, expecting researchers to justify every aspect of their study."

The head of a private research firm added:

"In the Philippines, IRBs can feel like they're dictating to researchers, assuming we lack knowledge. It's hard to accept when you know the boards themselves aren't perfect. My worst experience was receiving feedback meant for another study entirely."

Such experiences have led many researchers to adopt a pragmatic approach, viewing ethics approval as a procedural hurdle rather than a meaningful evaluation. A private-sector participant summarized:

"We mainly consider two things: speed of approval and cost."

A public health researcher further emphasized that once approval is granted, IRBs often disengage, leaving the responsibility of follow-up entirely on the researchers themselves. In practice, ethics approval becomes little more than a formal requirement, rather than an ongoing assessment of research conduct and impact. The time spent navigating the IRB process, this participant added, detracts from the actual preparation, analysis, writing, and publication of studies.

Some participants also expressed concern that IRBs may be contributing to a gatekeeping culture in research due to limited accountability. Despite the presence of PHREB, researchers highlighted the absence of feedback mechanisms or performance metrics to evaluate IRB efficiency.

These criticisms, however, reflect broader challenges within the Philippine research ecosystem. A participant from a firm handling outsourced hospital protocols noted:

"Our research landscape is plagued by inefficiencies, largely due to the lack of protected research time. In other countries, even junior researchers have dedicated time for research, which makes the system far more accessible.

Here, limited time undermines the quality of protocol writing itself."

A social scientist stressed that ethics should be an intrinsic part of research practice, extending beyond IRB approval. They added:

"At a minimum, IRBs should trust the researchers or rely on technical review boards that have already vetted the protocols. Currently, researchers craft protocols designed to pass ethics review with minimal scrutiny, rather than focusing on whether the study genuinely protects participants' well-being. Those are fundamentally different approaches."

Counterpoint: insights from IRB members

Researchers who have served on IRBs or currently hold membership often explain the logistical challenges of IRBs in the Philippines as a consequence of the country's still-developing research ethics system. One participant described the early stages of "building a culture of research ethics" as involving the difficult task of encouraging people to value and actively participate in ethics review by serving as board members. A Department of Health (DOH) participant noted that many hospitals lack dedicated budgets for sustaining IRBs, which forces boards to rely heavily on application fees to cover expenses like office space, administrative personnel, and secretarial support. A clinician-researcher added:

"IRB operations are bound by confidentiality and privacy requirements. Yet even large universities may lack lockable storage, and staff may be forced to share basic resources like fax machines or lack their own shredders."

Long review timelines can largely be attributed to understaffing and the heavy workload faced by IRBs. Members frequently juggle other roles, such as teaching or clinical duties, limiting the time they can devote solely to protocol evaluation. Compensation for IRB service is often minimal relative to the effort required. One participant illustrated this disparity:

"Reviewers may be asked to assess 300-page protocols but receive only an hour's worth of pay. It's perplexing that an IRB might charge PHP 60,000–70,000 [US$ 1,250–1,455] for review while compensating reviewers only PHP 1,000–2,000 [US$ 20–42] per protocol."

IRB members also emphasized a difference in perspective regarding the board's purpose. "Many researchers view IRBs as obstacles," said one member, noting that researchers often focus exclusively on the scientific aspects of their studies while overlooking ethical considerations. Complaints about repeated back-and-forth with IRBs, according to this group, often stem from poorly drafted protocols. Simple oversights—such as a study's objectives not aligning with its design—can trigger prolonged discussions.

These participants highlighted that the presence of technical review boards does not justify a less rigorous ethical review. As one member explained, preliminary technical assessments are helpful, but ethical reviewers often need to evaluate technical elements themselves because technical boards can miss issues that render a study ethically unsound. Ideally, they suggested, sufficient resources would allow a single committee to handle both ethical and technical reviews, streamlining the process. One participant added:

"When an IRB flags technical problems, it's not overreach or gatekeeping. It's about recognizing that a study affects real people and communities beyond the researcher."

A social scientist serving on an IRB illustrated this point with an example:

"Consider a study on COVID-19's impact on mental health with a sample of 400 participants. Asking intrusive questions to all 400 could unnecessarily increase risks to participants. Ethics review encourages researchers to question whether the same insights could be achieved with a smaller sample, prompting consideration of responsibilities that might otherwise be ignored if the focus were purely on scientific outcomes."

An issue of inequity

Overall, our findings align with global scholarship examining and critiquing the practices and culture of research ethics committees, starting with a recognition of their essential role: when confronted with the prospect of ethics review, most participants, echoing Schrag [16], reported an initial attitude of "eager cooperation."

However, as our study shows, the disconnect between researchers and IRBs extends beyond differing interpretations of what constitutes "ethical research." The challenges identified by Filipino researchers reflect broader, ongoing debates worldwide, including delays and burdensome paperwork in multisite studies as noted by Gold and Dewa [17]; ineffective evaluations stemming from imbalanced board composition, as highlighted by Schuppli and Fraser [18]; and review processes overly focused on clinical research, which Flicker *et al*. have argued may inadvertently place communities at risk, particularly in social sciences and

participatory research [19]. According to Abbott and Grady [20], the Philippine context similarly exhibits inefficiencies and inconsistencies across multiple dimensions, including fees, review timelines, and outcomes. Furthermore, although our data are limited, participants' accounts of profit-driven or commercialized IRBs resonate with concerns raised by Lemmens and Freedman [21] two decades ago regarding potential conflicts of interest, which could compromise review quality and public trust.

At its core, the ethics review system reflects inequity. The current framework disproportionately disadvantages researchers outside the academy, those affiliated with institutions or regions lacking accredited IRBs, independent researchers with limited funding, and those pursuing highly specialized topics. Even within institutions possessing IRBs, advantages skew toward researchers with ample funding or those whose topics are likely to attract support, contributing to what Patterson [22] terms "spaces of marginalization," privileging certain types of research and knowledge production over others.

Our findings indicate that non-clinical researchers are particularly affected by these inequities. For them, the system imposes what Schrag [16] describes as "silly restrictions" irrelevant to their fields, often enforced by IRBs lacking the expertise to appropriately evaluate non-clinical protocols. Boards operating with a predominantly biomedical lens may impose exaggerated "protectionist concerns" [23], which do not necessarily enhance ethical research practices [24]. Instead, current guidelines may unintentionally "[impede] ethically sound or potentially beneficial research" [25] and fail to account for complex, field-specific contexts highlighted in existing literature [26], exacerbating mistrust and sometimes even antagonism between researchers and IRBs [27, 28]. In the worst cases, the uncritical application of clinical research principles to non-clinical studies can promote inappropriate practices that undermine ethical conduct [24].

Ultimately, the burdens imposed by the ethics review process—whether relating to time, cost, geographic accessibility, or board expertise—interact to create a system that favors those with sufficient resources and fundable research topics. In this sense, ethics review is inseparable from considerations of (in)equity.

Recommendations

Addressing equity in health research ultimately requires broad systemic reforms, as noted by Pratt, Merritt, and Hyder [29], but more immediate interventions could improve the ethics review process and make it fairer. For instance, oversight bodies such as PHREB in the Philippines could adopt a more proactive role in mediating research culture debates, going beyond mere regulation to promote IRB proliferation and evaluate performance. Emphasis should be placed on what Coleman and Bouësseau [30] describe as outcomes assessment—ensuring that approved research is meaningfully implemented in the field. This does not undermine trust between researchers and IRBs post-approval, but highlights the need for boards to actively track updates from researchers or address ethical challenges that emerge after protocol approval; otherwise, ethics review risks being reduced to a symbolic "golden calf" of the research process.

Oversight committees could also help address the financial burden of ethics review by standardizing fees, mitigating potential conflicts of interest, and making approval more equitable while still allowing IRBs to maintain financial sustainability, as Emanuel, Lemmens, and Elliot [31] have argued. Our participants' frequent concern regarding insufficient material support for IRBs—covering staffing, office resources, and protected, compensated time for duties—underscores the importance of such financial self-sufficiency, a challenge recognized globally [20, 32].

Promoting equity should also involve supporting research topics that have historically received limited attention and fostering a more accessible environment for early-career, student, and independent researchers. As Chatfield *et al*. [33] emphasize, this requires staffing IRBs with appropriately qualified experts—given the absence of absolute standards for protocol evaluation, boards must rely on members' fair exercise of discretion and judgment [21]—while reducing bureaucratic obstacles that make obtaining approval unnecessarily labor-intensive. In other words, research culture should prioritize fostering "a culture of ethics" over a "culture of red tape" (Burris and Welsh in Coleman and Bouësseau [30]), allowing researchers to focus on study design, data collection, analysis, and dissemination.

Ultimately, a more equitable research culture would involve: (1) recognizing research as central to knowledge production across sectors, with adequate protected time and funding; (2) treating IRBs as essential partners and providing them sufficient human, material, and financial

resources; (3) viewing ethical research as an ongoing practice from protocol development to final analysis rather than merely as IRB approval; and (4) establishing trust between researchers and IRBs [34, 35], fostering a collaborative relationship rather than one based on "policing," as Makhoul [36] describes, where both parties function as allies rather than adversaries [32].

Conclusion

This study has several limitations. Our relatively small sample prevents broad generalizations about the Philippine health research landscape or definitive conclusions regarding subfields of research and IRB practices. Most participants were based in Metro Manila, limiting insights into regional experiences, and nearly half were affiliated with the state-funded UP system, potentially shaping their perspectives. Additionally, we did not include undergraduate students, and the focus on health research IRBs means our findings cannot be assumed to represent other academic or non-academic fields. Future studies could examine IRB practices in non-health research and the evolving landscape of multisite common review systems in the Philippines.

Despite these limitations, our study highlights lessons relevant to other low- and middle-income countries facing persistent research inequities. Participants' narratives reveal that, although IRBs are increasingly recognized as fundamental to research ethics, structural biases and deficiencies continue to challenge the landscape. Lindoff [37] underscores the importance of dialogue between researchers and IRBs, arguing that ethics review is essential even for non-medical research; we agree, but note that such partnerships can only thrive when the approval process ceases to act as a barrier. The goal should be a middle ground where researchers do not face systemic inequities before their studies begin, and where obtaining ethics approval does not require navigating a series of structural obstacles or "fighting" to be recognized.

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