

Technical Issues Encountered During Ethics Review: Quality Assurance in the Research Process*

In this issue, Pagkatipunan et al.¹ presented findings from a study on the status of research ethics committees among public and private higher education institutions located in the southern Manila area. Among the findings from their interviews with research directors and focus group discussions with faculty members was that there was a perception that the research ethics committee duplicated the technical review undertaken by the institution's research office, hence the non-existence of research ethics committees in these universities. Their findings resonate with the debates in the literature that argue the position that subjecting proposals to another round of technical review at the research ethics committee level is akin to double jeopardy.² This duplication of review results in inefficiencies in the system³ and draws the research ethics committees' attention away from the more important ethical considerations of the proposal that they are supposed to assess. Those who advocate this argument also challenge the quality argument as there is no empirical evidence showing that the quality of a research project was improved because of the technical inputs from the research ethics committee.

Despite this, we still operate on the current policy of research ethics committees, which is to require the submission of proof of prior technical review before proposals are accepted for initial ethics review. This stems from three ideas that fall under the broader argument that bad science is bad ethics.⁴ At its heart, this position advances the idea that scrutiny of the design aspects of a study is but another layer in the many rounds of peer review that a research idea must go through as part of a vetting process that upholds society's trust in science. Hence, this concept was enshrined in international and local ethics guidelines.

Now, it has been reported in the literature that ethics committees return about three in five protocols because of a design-related query and that, overall, queries contained in a decision letter will be about a technical issue 30% of the time.⁵⁻¹⁵ The five most frequently cited design-related issues identified during ethics review include justification for the study, study design, sampling, data collection, and data analysis.⁸⁻¹⁴

After being involved with research ethics committees over the past several years, I would like to propose four reasons why these design issues are still present and detected at the research ethics committee level. *First, we must recognize that there are many ways of knowing, and academics and scholars can investigate a question using different paradigms.* Issues may arise if there is a dissonance or difference in the way the researcher and the research ethics committee see the world. A typical example would be when a researcher submits a study grounded on a constructivist approach to a panel that is mainly, if not purely, positivist in orientation. But it is also possible to have the debate within the same tradition, such as in statistics, where frequentists and Bayesians hold differing ideas about probability. And even when ethics committees do recognize that there are many ways of knowing, *the ethics committee may lack the expertise to appropriately review a submitted proposal*, either because they do not have the member or consultant with the required know-how, or their expert may no longer be up-to-date in their knowledge. The reverse is also possible, that is to say, that the deficiency may be on the side of the technical panel, and it is the ethics committee expert who can spot the issues that were initially missed. This leads me to my third point, which is *a possible lack of trust in the review conducted by the technical panel*, especially if the ethics committee has repeatedly encountered proposals of poor quality vetted by that group. Lastly, we cannot discount the fact that *the quality of the written protocol may also be a determining factor*. In short, the proponent may have the right ideas about the technical aspects of a study but is not able to translate these into words that are comprehensible to the reviewer.

I end by providing some recommendations for stakeholders so that the issues I mentioned earlier can be addressed. Since the proposal originates at the level of the researcher, it is important that the proponent ensures that the document is not only clearly written but is also aligned with the best research practices in the discipline. The technical panel should perform its function with fairness, integrity, and objectivity in mind. As to the research ethics committee, I think it is important to not only broaden the world view of the members in research approaches but also ensure that members (or consultants) have the appropriate expertise required for reviewing a proposal. Perhaps the ethics committee can undertake an annual review of the types of proposals encountered and determine if additional members or consultants are needed. Reviewers should also be able

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to discern and learn to disclose when a proposal is already beyond their expertise so that it can be assigned to another member (or consultant). And for proposals accepted for review, the reviewer's focus should be on whether the proposed approach is logical and appropriate to the study objectives and not on whether it follows the best approach outlined in textbooks. Emanuel and colleagues,¹⁶ in presenting the seven ethical requirements two decades ago, opined that scientific soundness is rooted in two important considerations. First is validity, and the second is feasibility. This means that researchers may be constrained in their study methods by practical considerations, which is why their proposal is less than ideal. Of course, this constraint must be clearly explained in the protocol for the appreciation of reviewers.

In summary, there is value in assessing the technical merits of a proposal, even at the level of the research ethics committee. However, taking on this responsibility requires that research ethics committees possess the necessary capacity to undertake a meaningful review of the design aspects of the proposed research.

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Disclosures

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