
Letter to the Editor

Health Policy and Systems Research Ethics Review Requires Global Participation, Iteration, and Adaptation

To the Editor:

We were elated to see our article, “Operationalizing the Ethical Review of Global Health Policy and Systems Research: A Proposed Checklist,”¹ inspire much needed discussion on the topic of health policy and system research (HPSR) ethics. We are grateful that the *Journal of Law, Medicine & Ethics* has created an avenue for dialog, and we thank the editor for the opportunity to respond to Govind Persad’s recent commentary on our paper entitled “Improving the Ethical Review of Health Policy and Systems Research: Some Suggestions.”² When we first began thinking about the ethical uniqueness of HPSR and its distinction from clinical and related human-subjects public health research nearly a decade ago,³ our goal was to foster a dynamic, fair, and communal international dialogue toward a valid and sound process of addressing and responding to the ethical issues unique to HPSR — especially in low and middle-income countries (LMICs). To that end — and as we have stated in our paper — our proposed checklist should be seen as a summary of those efforts and is meant to be iterative and adaptive.

In reading Persad’s commentary, we were pleased to receive his suggestions on the nature of the checklist itself. We agree that identifying *who* the most relevant parties are in reviewing HPSR need to be decided at all levels. As we have previously shown, most research ethics review committees (RECs) are not adequately equipped to review, appraise, or identify the salient ethical challenges for LMIC HPSR.⁴ However, given that there are current ethical review mechanisms in place — albeit for clinical/human-subjects research — we suggest that perhaps these mechanisms may be an appropriate starting point and could be modified in the short-term to accommodate the ethical review of HPSR. We agree, and repeatedly state throughout our paper, that each component/section of our checklist should not be taken as definitive, but subject to deliberation. While we have proposed these checklist sections as basic considerations in the ethical review of HPSR, we do appreciate the mandated versus encour-

aged (or required versus recommended) suggestion and hope this leads to more conversation on what falls under which category. We also agree that HPSR studies are unique, and some studies may not exactly fit under the global justice or ethical considerations we have outlined. However, it is important for researchers and RECs alike to participate in a joint deliberative process to decide what aspects of any proposed HPSR study require additional ethical considerations.

However, we question the conclusion Persad draws about the construction of the ethical framework that informs the checklist. As we have made clear in our methods section, the ethics frameworks that inform the current iteration of our proposed HPSR checklist is in fact grounded in research ethics, public health ethics, implementation research, and global justice frameworks. These frameworks are also in part informed by some of the higher-order ethics philosophy outlined in the “principlist” framework. For our purposes, we did not find it useful to view the principlist paradigm as a distinct framework, but rather as a starting point for considering our ethical duties in the larger context of what is owed to those impacted by HPSR. We hope others recognize this alternate reading of the principlist paradigm and are able to review the cited literature we provide throughout our methods section.

Persad also raises many specific points within the checklist itself. We agree with Persad’s discussion on the challenges of identifying legitimate representatives in the setting of institutional-level consent when individual consent is infeasible. The HPSR example of conditional cash transfers within our paper should not distract from identifying how best to obtain consent at the institutional-level. We invite other colleagues who work within this space to share some of their examples as well with the aim of creating a repository of HPSR didactic case studies.

We also share Persad’s concerns that current RECs may place an inappropriate amount of focus on incentives and hyper-scrutinize its effect on autonomy. However, we also cannot help but to consider the very real ways in which poverty affects decision-making among the super vulnerable — which should not be underestimated or overlooked when considering the use of incentives. Ultimately, RECs may require additional training to appropriately apply the checklist.

Furthermore, Persad's analogy of incentives for performing less-desirable work requires further clarity because participating in health research versus performing labor have arguably different ontologies and teleologies that do not render the comparison entirely appropriate. Regardless, it is clear that role of incentives in HPSR merits further discussion. Additionally, we agree that further clarification of the research-community relationship that Persad raises later in his commentary warrants more exploration too.

A major point of disagreement with Persad — and point of caution — is the implication that ethical scrutiny of HPSR interventions can promote exceptionalism and be counterproductive. Forgoing ethical review undermines our commitments to protecting those worst-off from harm, abuse, and exploitation. As we have articulated before, what differentiates our call for a more robust ethical review of HPSR is our commitments to global justice.⁵

It is true that governments, corporations, or philanthropists could (and often do) implement interventions in LMICs without a review process. However, as we have seen and continue to see — these interventions are often implemented with little knowledge of effectiveness, efficiency, or longitudinal impact. Without such investigations or evaluations — the worst-off, especially in LMICs, will continue to be negatively impacted. HPSR has a distinct function of *understanding* the best strategy, issue, or intervention for a particular system. The most successful policies are those that are well-informed, but in the process of obtaining that information, we must also ensure that the knowledge-generating/gathering process is not exploitative or abusive to systems, institutions, or individuals who are worst-off.

The suggestion that “valuable research” may be obstructed if quality ethical review is expected is disconcerting; it is this very excuse that has led to more stringent human-subjects protections in clinical research globally. We generously read Persad's discussion of research exceptionalism as identifying a gap where HPSR interventions *could* and *have* circumvented ethical review (in similar ways to the discussions on comparative effectiveness research or patient-centered outcomes research). Our ultimate concern is for the LMIC entities that have much to lose at the hands of poorly thought-out interventions

that have avoided ethical review. As we are seeing in other fields, there is much at stake when interventions are not appropriately designed, studied, and reviewed.

Our checklist is a step toward a more robust HPSR ethics review process. It is designed to advance efforts in the appropriate training of RECs (in the US and globally) and the systematization of HPSR ethics review. A more deliberative process is needed from the global HPSR community to develop the training tools and processes necessary for appropriate HPSR ethics review. We hope others are inspired to engage in a global deliberative process required to strengthen the ethical review of HPSR.

References

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