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EDITORIALS

REPORTING ETHICAL PROCESSES IN JOURNALS

The responsibility to ensure that research is conducted ethically rests with a number of individuals, including investigators, sponsors, research ethics committees (RECs), journal editors, participants, and the public. Arguably, a particularly powerful mechanism to encourage ethical research is the requirement stipulated by leading international bodies of journal editors[1-3] that authors include in their manuscripts submitted for publication, written statements confirming that REC approval and informed consent had been obtained before commencement of the research. Indeed, were publications conditional on such compliance, editors would become the ultimate gatekeepers of ethical research.[4] A companion article in this publication examines how two Indian pediatric journals perform this watchdog function.[5] Unsurprisingly, given similar findings in the growing literature in this field, the authors describe low levels of documentation of basic ethical safeguards, namely, REC approval and informed consent, during 2006. Importantly, as the authors caution, failure to document REC approval and informed consent in a journal article does not necessarily imply that the research was unethical, nor is it evidence that researchers failed in their ethical obligations or that participants were put at risk. There are many reasons, including lack of space, a belief that these requirements reflect standard practice and therefore need not be reported, or nonspecification of ethical requirements in journals' instructions for authors, that might explain authors' failure to *document* compliance. In other words, these data do not reflect *actual* failure of compliance during the conduct of a study; in fact, a follow-up survey of investigators who did not mention REC approval showed far higher rates of compliance than originally reported.[6]

These findings raise interesting questions regarding the responsibility of journal editors in the chain of ethical protections. Should journal editors be the final arbitrators of ethical research and is the existing focus on documentation of informed consent and REC approval a reasonable and adequate reflection of important ethical concerns facing international biomedical research?*

I would argue that the current emphasis on reporting individual written informed consent and assent fails to capture, and may even entrench, other well-described problems

*In this commentary, I do not address reporting policies for conflict of interest and authorship.

relating to the validity of much written consent, particularly where research is conducted in developing countries.[7] These include, among others, the therapeutic misconception, low literacy levels, limited understanding of research and science, the need for community consent and consultation, and the fact that voluntariness is often compromised by the opportunity provided by taking part in research to access better health care. In similar vein, there are growing doubts about research ethics committees' independence and their ability, in the face of mushrooming bureaucracy and regulation, to protect participants' rights and welfare.[8] Following the highly publicized death of a healthy volunteer taking part in a study at a leading institution in the United States (US), a bioethicist was moved to state publicly that the US system for protecting human subjects 'is not simply sick – it is dead.'[8] In turn, the advocacy group, Public Citizen Health Research Group, had this to say: '… if protections are flawed at esteemed places such as Hopkins, they are surely flawed elsewhere.'[9]

In light of these criticisms, is there room for expanding the present procedural focus on documentation of informed consent and REC approval to include other substantive ethically relevant pointers of biomedical research? An indicator of exploitation, meaning the unfair distribution of the benefits of research, would certainly shed some light on how, in practice, the benefits of research are shared among participants. Sponsors who go the extra mile and provide post-trial access to safe and efficacious interventions would surely welcome such a move, not least because of accompanying publicity. Conversely, companies who refuse to provide benefits to populations taking part in their research might be encouraged through fear of negative exposure to reexamine their responsibilities. But this is contentious; and a valid definition of exploitation, including prior agreements, requires much more intellectual work.

In conclusion, if editors believe they have a meaningful role in promoting ethical research, perhaps they should look at extending existing yet narrow reporting requirements to include other equally important indicators of ethical research, especially in a time of globalization of clinical research.[10] Editors need to identify ethical indicators specifically relevant to international research undertaken in low-income countries. Alternatively, current benchmarks,[11] if appropriately operationalized, might serve this purpose.

Finally, to be effective gatekeepers, editors must ensure consistent and uniform application of reporting guidelines for ethical research outlined in their instructions for authors and underlined by international governing bodies. Only, once authors know for sure that publication is conditional on documentation of basic ethical practices, preferably spanning the duration of a study, are they likely to comply fully with journals' reporting requirements.

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