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 editors would become the ultimate gatekeepers of ethical research.

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 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 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.’[9] 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.

REFERENCES


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

128


LESLEY HENLEY
Institute of Child Health, School of Child and Adolescent Health, Red Cross War Memorial Children’s Hospital, Rondebosch 7700, South Africa

Correspondence:
Lesley Henley PhD
Institute of Child Health
School of Child and Adolescent Health
University of Cape Town
Rondebosch 7700, South Africa
E-mail: lesley.henley@uct.ac.za

Figure 1: Excuses offered for lack of reporting of ethical research

Can be extrapolated to other biomedical journals in India. However, one of the major limitations of the study was that the individual authors were not contacted to determine the reason(s) for nonreporting of ethical processes. This mattered a lot. It would have not only documented the discrepancy between what was done and what was reported but also the reasons thereof. Absence of a statement does not automatically imply that consent was not taken. Many a times (for example, letter to editor) due to shortage of space or ignorance of writing style, this may not be mentioned. On the other side (for manuscripts which reported adherence to ethical processes), it was also important to determine whether the process of such reporting in itself was ethical or not.

MISSED OPPORTUNITIES

There is a lack of exposure to culture of reporting medical research (ethics, in particular), starting right from the undergraduate days in the medical school. Even later, such opportunities are far and few in between. As a result, most of the authors (researchers) in India are ill informed about, and poorly equipped with, the process for obtaining ethical clearance, access to tools for taking consent, and requirements for assent, etc.

During undergraduate days, though a medical student learns about medical ethics, consent, and assent while studying forensic medicine, there is hardly any emphasis, during clinical training, on its application. Also, students are not supposed to do research. (In fact, it is discouraged; an undergraduate medical student I closely know drew up a research project, only to be told by the concerned authorities, “This is not your job, you only study, write the exam, get the degree, and then do whatever.”) No wonder, the flowers don’t bloom. A laudable initiative is the Indian Council of Medical Research (ICMR) Student Fellowship that promotes research by medical students and also exposes them to the tools of research methodology, including ethical considerations. However, the proportion of students applying for and ultimately executing such research is very low, compared to the total number of medical undergraduate students in India.

Every postgraduate student is supposed to write a dissertation/thesis before the degree is awarded. Most of the time, the protocols are presented, discussed, and approved in departmental/institutional meeting and ethical clearance is presumed. There is no formal approval of the institutional review board (IRB), because the IRB either does not exist or remains nonfunctional. Of the more than 250 medical colleges in India, not more than 20 (a rough estimate) have a properly constituted institutional advisory board/ethical committee