

Implementing research ethics

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In this epoch of progress in health care, when systematic generation of knowledge is considered the cornerstone of health development, there is increasing focus on the need to demonstrate the ethicalness of doing research. Stories of harm inflicted on research participants

and scientific misconduct in research are rife in the history of science, even within our immediate past.¹ The lessons that we have learned from these stories have shaped the ethical research guidelines that we abide by and uphold today.^{2,3}

Within the last 15 years, since the creation of the Philippine Health Research Ethics Board (PHREB) as the country's policy-making body on research ethics, numerous mandates have been issued to ensure human research participant protection and research integrity. Taken together, these mandates push for the ethical review of researches that are proposed to be done among humans or to use human data, the establishment of research ethics committees (RECs) in institutions that produce these researches, and the maintenance of quality standards in the operation of these RECs through accreditation by the PHREB.⁴ The enactment of Republic Act No. 10532 in 2013, formally institutionalized the Philippine National Health Research System and tied up all these mandates that pertain to research ethics.⁵ In effect, all institutions that generate human research—hospitals, health facilities, pharmaceutical companies, government and private agencies, universities, colleges, and even high schools—are expected to comply with these mandates.

Many institutions that produce research involving humans or human data find it very challenging to set up a series of procedures for the review of these researches. For one, submitting research protocols—after they have gone through several revisions as directed by the technical research committee or panel—to a second committee for ethics review, approval, and implementation monitoring is a relatively new practice. The extra layer of scrutiny, the intellectual disagreements of technical committees and RECs, and the additional time and effort it takes to get an REC approval all figure

in the arguments of those who are against the ethics review process. Research offices or training committees may have to put a system in place to incentivize submission or discourage non-submission of research protocols for ethics review. All in all, it takes administrative political will to incorporate a procedural pathway to ethics review into the usual research generation procedures of an institution.

The institutions can arrange a mechanism for external ethics committees or, more commonly—and indeed more efficiently—they can create their own in-house RECs. The demands related to the establishment and operation of in-house RECs constitute an altogether different set of challenges for the institution. REC members and staff will have to be trained to competently do ethics reviews and perform administrative tasks within the REC office. There is also the difficulty of coming up with a good roster of trained reviewers who can dedicate time for committee work. The institution will also have to allocate physical space, and finance both the cost of REC operations and the remuneration of office personnel.

The REC accreditation process is meant to reduce variation of procedures and maintain the quality of operations by way of recommending certain standards in the structures, processes, and outputs of RECs. On the part of PHREB as the accrediting body, the process requires careful organization of a well-trained accreditation team that can efficiently and scrupulously evaluate the REC operations and produce helpful recommendations. The process is inherently challenging for REC managers as well since, most of the time, it requires meticulous (re)engineering of REC operations.

Above all these demands in complying with the mandates on research ethics is the pervasive call for us to generate trustworthy research results in ways that are beneficial and non-harmful to humans. An ethically produced piece of knowledge is a valuable contribution to scientific progress.

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Received

21 March 2021

Accepted

30 April 2021

Published online

19 May 2021

Cite as

Concha AS. Implementing research ethics. *SPMC J Health Care Serv.* 2021;7(1):5. <http://n2t.net/ark:/76951/jhcs83ex2a>.

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Article source

Submitted

Peer review

Internal

Competing interests

None declared

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