

## Could Ethics Committees please welcome Independent Researchers?

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The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. Declaration of Helsinki was adopted by the 18<sup>th</sup> WMA General Assembly in 1964. Up to now, there were 2 notes of Clarification added in 2002 and 2004 and altogether 7 amendments with the last one in October 2013 [1].

Preamble; General Principles; Risk, Burdens and Benefits; Vulnerable Groups and Individuals; Scientific Requirements and Research Protocols; Research Ethics Committees; Privacy and Confidentiality; Informed Consent; Use of Placebo; Post-Trial Provisions; Research Registration and Publication and Dissemination of Results; and Unproven Interventions in Clinical Practice are stated clearly in Declaration of Helsinki [1]. The Declaration mentions that “Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research.” “Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.” “The research protocol must be submitted to Research Ethics Committees for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins.” [1].

International Committee of Medical Journal Editors gives a series of recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals including “when reporting research involving human data, authors should indicate whether the procedures followed have been assessed by the responsible review committee (institutional and national), or if no formal ethics committee is available, were in accordance with the Helsinki Declaration as revised in 2013. If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. Approval by a responsible review committee does not preclude editors from forming their own judgment whether the conduct of the research was appropriate” [2]. There is a list of journals following the recommendations of International committee of Medical Journal Editors [3].

Most researchers can find the corresponding Research Ethics Committees in their affiliated hospital, institution or university, etc. There are more than 200 HRECs in institutions and organizations across Australia [4]. A list of Institutional Review Board in Office for Human Research Protections (OHRP) can be found in their link [5]. More ethics committees can be found in the link of World Health Organization (WHO) [6].

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How about independent researchers? Independent researchers asked where they can go to apply and how to solve problem related to ethical approval. There has been discussions about ethics approval issues among them online [7-8]. They can co-operate with other researchers who are affiliated with institutions; form an ethics committee [9]; approach private ethics committees.

Problems may also arise in co-operation with other researchers. Some Ethics Committees only accept submission of protocols which the Principal Investigator is the member, student or staff [10-12], the original principal investigator has to become co-investigator in order to have their application received. There is also politics in forming an ethics committee, university and hospital staff may not be allowed to voluntarily join the board of other ethics committees even in their leisure time. In such circumstances, submission of protocol to private ethics committee is the remaining choice. Some Ethics Committees may not have enough staff for large amount of applications or have difficulty finding experts for reviewing protocols beyond their expertise (e.g. Hong Kong Clinical Research Ethics Committee [13], Hong Kong Doctors Union [14]). These committees usually have a pre-screening process. They may simply decline to pass the protocol to their review board and suggest applicants to go to another ethics committee.

Independent researchers may face another problem if they approach commercial/private ethics committees [15-18]. These committees may be overseas and they will co-operate with the local ethics committees. This arrangement complies with The Declaration of Helsinki which stated that the Research ethics committee “must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in the Declaration” [1]. In some circumstances, local ethic committees initially refused to read the protocol then become willing to do so when overseas Ethics committees are engaged. If they can actually do it, why didn't they do so before?

The fundamental aims of overseeing Human Research are to protect the rights of the human subject and to guarantee their safety and dignity. The implementation of such process should not switch to a conflict of power and benefits among researchers from different backgrounds. Researchers are graduates or staff of universities, could universities consider to read the protocols submitted by those graduates who had experience as being principal investigators in college? Could the Alumni Associations of universities liaise, co-operate or form ethics committees to assist the alumni? Will it be actually more constructive to the universities? Is the contribution to the mankind more important? As a member of the scientific community, shall we think about fairness?

### **Declaration of Conflict of interest**

The author is currently an independent researcher.

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