Addressing Procedural Challenges of Ethical Review System: Towards a Better Ethical Quality of Clinical Trials Review in Malaysia

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Received 16 Oct 2018, Accepted 04 Dec 2018, Accepted author version posted online: 11 Dec 2018

Abstract

The review of clinical trials with human participants in Malaysia is governed by a decentralized control system. The clinical trial protocols are reviewed by 13 registered research ethics committees (RECs) in Malaysia. A governmental body, the National Pharmaceutical Control Bureau, is responsible for the inspection and oversight of these registered RECs to ensure that they comply with the regulatory requirements. However, this study highlights that each REC in Malaysia has a different standard operating procedure and ethical review process. Other procedural challenges identified include inadequate membership, poor mechanism for research monitoring after ethical approval, and insufficient resources. Establishments of a national standard of REC and a central ethics